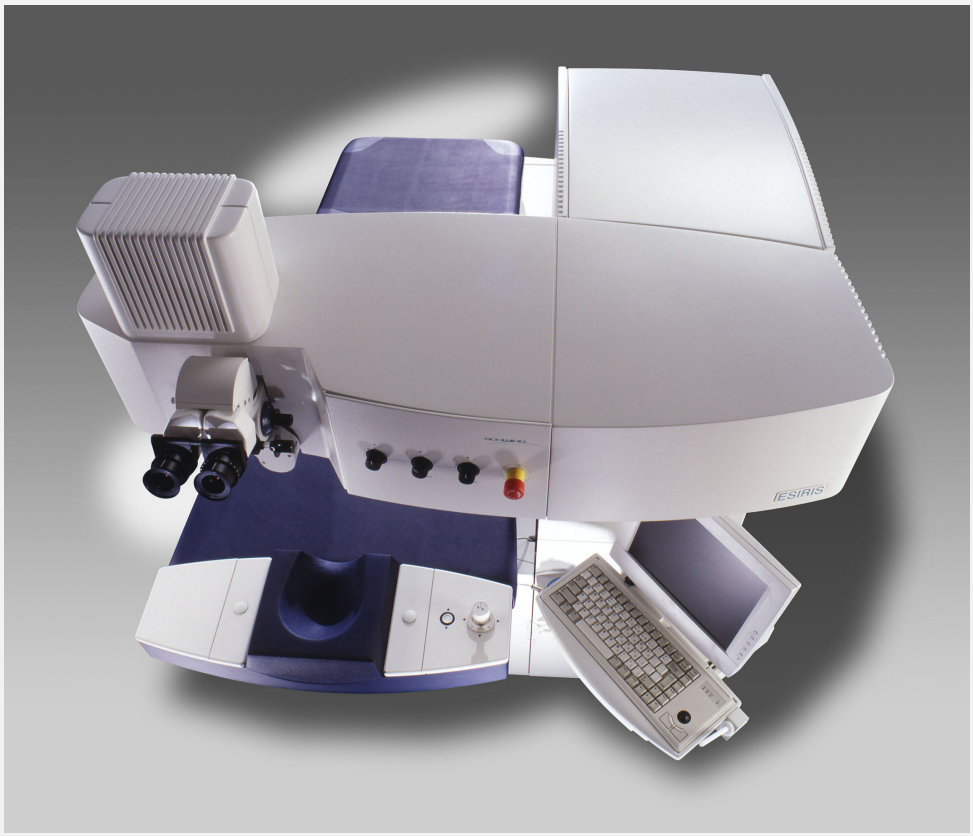
SCHWIND

eye-tech-solutions

EXCIMER LASER
ESIRIS

USER MANUAL

Valid for Software Version 2.6.2



SCHWIND eye-tech-solutions GmbH & Co. KG
Mainparkstrasse 6-10
D-63801 Kleinostheim

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CE 0483

Dear Customer

Thank you very much for purchasing this medical product and the confidence you have in our company. You have decided on a sophisticated product, which was manufactured and tested under strict quality criteria.

Construction and production fully complies with regulations and requirements which apply to medical products.

Compliance with all effective standards and laws is clearly visible by the CE symbol, which is displayed on the type label (refer to chapter 3.3 Unit Labelling). The CE Symbol stands for conformity with current laws and consequently for security and confidence.

Constant research and development may cause changes in design and scope of supply. Therefore, in individual cases, the figures in this manual might deviate from the delivered product.

If you have any questions or desire further information about your equipment, please do not hesitate to contact us via phone, fax or e-mail. Our team of specialists will be glad to help you. Our address, phone and fax numbers, as well as the e-mail address can be found at the beginning of this manual in chapter GENERAL INFORMATION.

Sincerely,

SCHWIND eye-tech-solution GmbH & Co.KG

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GENERAL INFORMATION

System Identification Data

Name of device: **SCHWIND ESIRIS Excimer Laser System**

Device type: **Ophthalmologic laser equipment for corneal tissue ablation**

Software version: **2.6**

Serial number: **E xxx**

Medical device class: **IIb**

Manufacturer

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Technical Assistance / Application Support

SCHWIND eye-tech-solutions offers a comprehensive warranty and service support program. Included in this program is our service package.

Highly qualified representatives from our SERVICE and COSTUMER SUPPORT department are available to support you and to solve any operational problems.

Should you have any questions, please do not hesitate to contact our Service Hotline. The Service Hotline is free of additional charges.

Service Hotline

SCHWIND Service Hotline:

Tel.: +49-(0)-6027-508 - 333

Fax: +49-(0)-6027-508 – 245

mailto:service@eye-tech.net

Our customers outside of Germany should use the service hotline provided by our local distributor or authorized Service Representative first.

Application Support

SCHWIND Customer Support:

Fax: +49-(0)-6027-508 – 208

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Documentation

The purpose of the user's manual is to familiarize the operator(s) of the SCHWIND Esiris Laser with the safety instructions, set-up, handling, operation, and maintenance procedures of the system.

The following documentation is supplied with the laser system:

- User Manual
- Medical Apparatus Book
- Operation Manual
- Service Information
- Esiris Brochure

Declaration of Manufacturer MPG [1]

The SCHWIND ESIRIS Excimer Laser System has been developed according to the Medical Product Code MPG. The manufacturer SCHWIND eye-tech-solutions has been authorized through the named "MDC" office KZ 0483 to produce products for medicinal purposes and to market them.

Conformity with the construction authorization of the device according to MPG is ensured under the following preconditions:

- Delivery is executed by SCHWIND eye-tech-solutions or adistributor which is authorized by SCHWIND eye-tech-solutions;
- All service and maintenance work is performed only by personnel which is authorized by SCHWIND eye-tech-solutions;
- Accessories, consumables and disposables are authorized only if completely safe operation is confirmed through a device test performed by an authorized testing authority. This is especially important for the patient bed.

[1]) MPG – Medizin-Produkte-Gesetz is the German Medical Product Code

Declaration of Conformity

Declaration of Conformity

According to Council Directives MDD 93/42 EEC

Manufacturer:	**SCHWIND eye-tech-soultions GmbH & Co KG** Mainparkstraße 6 - 10 D-63801 Kleinostheim Germany
Description:	Laser Equipment for Ophthalmology
Application:	Corneal tissue ablation, refractive surgery
Type:	Schwind **ESIRIS** starting with serial number: E xxx

This is to certify that the above mentioned product complies with the following regulation for medical devices

Council Directives MDD 93/42/EEC

from June 14th , 1993

Any modifications to the product, not authorised by us, will invalidate this declaration

Kleinostheim, 06th November 2003

CE 0483

Rolf Schwind	Claus Elsner
President & CEO	Safety Inspector

Status of the ESIRIS User Manual

Edition	Date	Changes / Remarks
Version 1.0	22.09.2000	
Version 1.2	27.03.2001	
Version 2.0	06.02.2002	The version 2.0 contains changes in following chapters: ▪ General Notice to Users ▪ 1. Safety Instructions ▪ 2. System Description ▪ 4. Device Control ▪ 5. Description of Menu Points
Version 2.01	05.05.2002	The version 2.01 contains changes in following chapters: ▪ 2.2 Technical Data ▪ 2.6 Optical System ▪ 2.9 Patient Bed ▪ 4.3 Bed Control Type A ▪ 4.4 Bed Control Type B ▪ 4.5 Operation of the Excimer Laser ▪ 4.6 Start a Treatment ▪ 5. Selection of Procedures and Tests in Main Menu
Pre-Version 2.5 **(English only)**	05.07.2003	General revision of all chapters, adaption of the Software Version. 2.5. **IMPORTANT NOTE** **In the final version the following functions will be in more detail explained:** ▪ **Database input** ▪ **Recovery**

Version 2.6	2003-09-30	Revision of following chapters: 2.2, 2.5, 9.3. Explanation of additional functions: ▪ Export of log file and treatment data in Help Menu – chapter 7.6.1. ▪ Flap Countdown – chapter 8.3.3.4. ▪ Input of Patient Data – chapter 8.5 ▪ Performing of ORK treatments – chapter 8.6 ▪ Recovery function – chapter 8.7
Version 2.6.1 Released: CE /17.11.2003	2003-11-13	Declaration of Conformity A new chapter added: 8.8 Accounting Routin Revision chapter 1.4 Warranty– points 7), 8), 9) added.
Version 2.6.2 Released: VH/SF 12.03.2004	2004-03-12	**Chapter 6.10.1.3 'Registration'**: IMPORTANT NOTE added. **Chapter 8.3.3.1 'Input of Patient and Treatment Data':** Information regarding Nomogramm and IMPORTANT NOTE added. **Chapter 6.10.1.4 'Function Choose Nomogram'**: Description extended. **Chapter 8.3.3.3 'Eye-Tracking'**: Description extended

How to Use the User Manual

This manual contains information for the installation and use of the SCHWIND ESIRIS Excimer Laser System. The efficiency of this device depends on proper use and maintenance.

The User Manual consists of the section "GENERAL INFORMATION" and 10 chapters as listed below.

The overview table shows you the brief content of each chapter.

Chapter	Name	Short Description
	GENERAL INFORMATION	Table of Contents, List of figures, How to use the user manual, Declaration of Conformity, Declaration of Manufacturer.
1	INTRODUCTION	Short description of the laser system and the application of the Excimer Laser.
2	SAFETY	General information regarding safety operation of the Excimer laser ESIRIS, Regulations for medical devices, Safety regulations laser system.
3	SYSTEM DESCRIPTION	Detailed description of the Excimer laser system and components.
4	TECHNICAL DATA	Technical data of Excimer laser ESIRIS and functional units.
5	INSTALLATION	Description of the required procedures for delivery, unpacking and installation of the Excimer laser ESIRIS
6	DEVICE CONTROL	Description of functions and procedures required for the safe operation of the Excimer laser ESIRIS.
7	SERVICE PROCEDURES	Description of software-managed procedures in main menu such as fluence test, drift test, gas change, and PMMA test.
8	TREATMENT SELECTION	Description of software managed PTK, PRK/LASEK and LASIK treatments in main menu.
9	CLEANING AND MAINTENANCE	Description of procedures required for cleaning, sterilisation and maintenance of the ESIRIS.
10	Appendix	

IMPORTANT NOTE

Read this User Manual carefully before starting operation of the SCHWIND ESIRIS Excimer laser system.

1. INTRODUCTION

1.1. The Product

The SCHWIND ESIRIS Excimer laser system is a medical high-performance laser which will be applied for the permanent corrections of the various kinds of ametropias and corneal changes of the human eye in the refractive surgery.

The Excimer laser represents the latest and most innovative technology for refractive surgery.

1.2. System Description

The ESIRIS offers customized treatment possibilities in refractive surgery such as the correction of aberrations of the human eye and modulations of the cornea.

The ESIRIS uses cold light (wave length 193 nm) and ablates the desired corneal tissue of the human eye very precisely and computer controlled. This is carried out on the corneal surface (PRK), or first a thin layer is removed in order to have the laser ablate the layer underneath (LASIK).

ESIRIS – the new Excimer Scanning Spot Laser offers the following benefits:

- Optimal surface quality during the ablation process by high pulse frequency – 200 Hz scanning spot.
- Optimal centring by high speed Eye Tracker (patent pending).
- Correction of myopia and hyperopia, with or without astigmatism.
- Immediate hyperopia and myopia treatments.
- Pure Astigmatism correction with positive and negative cylinder.
- Optimal security by sophisticated integrated safety features.

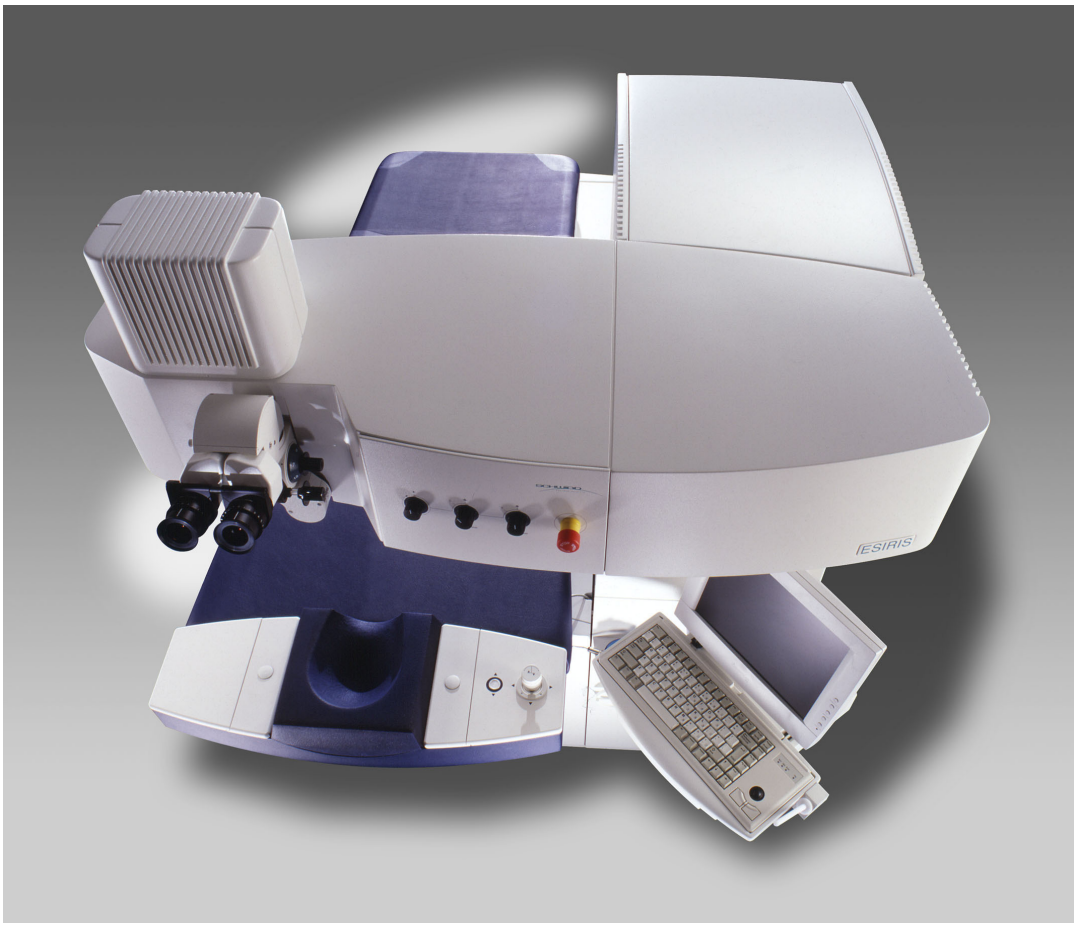


Figure 1: SCHWIND ESIRIS system

1.3. Liability of the Manufacturer

SCHWIND eye-tech-solutions do not assume any liability for:

- Injuries to persons, uless it is caused by intent or gross negligence,
- Damages of properties,
- Damages / destruction of equipment or software,
- Data loss ,
- Financial, legal, commercial and productivity-related disadvantages for the company and the personal user,

Due to the following course of actions:

(1) Any attempt to alter, modify or manipulate the product in a way not stipulated in the User Manual of SCHWIND eye-tech-solutions.

(2) Manipulation, alterations or damages to the SCHWIND ESIRIS Excimer Laser System and to the software by technicians not authorized by SCHWIND eye-tech-solutions or other third parties.

(3) Use of accessories, spare parts and/or Laser systems, software which are not specified for application with the ESIRIS.

(4) Non-observance of the laser operating notes, warning symbols and safety instructions while operating the ESIRIS.

(5) Operational error of user.

(6) Computer virus.

(7) Excessive force.

(8) Power failure, voltage fluctuations, electromagnetic interference.

(9) Erroneous deletion of data by the user.

(10) Negligence of the user.

1.4. Warranty

IMPORTANT NOTE

The duration of the warranty period for the SCHWIND ESIRIS Excimer laser system is 12 months.

(1) The warranty period begins with the first start-up of the device after signing of the delivery note by the client.

(2) Warranty includes all defects of the device caused by defective parts or manufacturing faults. Malfunctions that are not caused by improper use are repaired under warranty. Damage caused by abuse or improper use is not repaired under warranty.

(3) The legal warranty applies only to parts that are replaced or repaired by SCHWIND eye-tech-solutions.

(4) Damages or malfunctions have to be reported to SCHWIND eye-tech-solutions or to the representative immediately.

(5) The damaged parts have to be sent back to SCHWIND eye-tech-solutions. When returning defective parts, please use the original packing or coordinate alternate packing with SCHWIND eye-tech-solutions.

(6) Deficiencies that arise from:

- Non-standard or extraordinary use,
- Repairs without original parts,
- Incorrect treatment of the device,
- Inspections, services, device modifications or any form of manipulation of the system performed by unauthorized personnel

Will void the guarantee and will relieve SCHWIND eye-tech-solutions from any responsibility.

(7) SCHWIND grants no other warranty, either express or implied, concerning the above mentioned parts and their documentation. Any implied warranties of merchantability and fitness for the particular purpose are disclaimed.

(8) SCHWIND shall not be liable for incidental, consequential, indirect, or special damages of any kind, loss of information or data, or other financial loss arising out or in connection with the sale or use of the product, whether based in contract, tort (including negligence) or any other theory.

(9) The above mentioned exclusion of liability is void if the cause of damage is based on intent or gross negligence. Furthermore, it does not apply to damage due to lack of a warranted quality and claims under product liability.

(10) Product improvement initiatives based on technological development are not grounds for free of charge system upgrades.

(11) The General Conditions for Sale, Delivery and Payment of SCHWIND eye-tech-solutions are generally to be considered.

In addition, please refer to chapters “Manufacturer’s Responsibility” and “Liability of the Manufacturer”.

1.5. Data Loss

SCHWIND eye-tech-solutions is not liable for any data loss occurred due to reasons described in the following chapter.

1.5.1. Protection against Data Loss

- Do not use diagnostic tools.
- Use virus-free storage media for your data.
- Do not install any additional software on your ESIRIS system.

1.5.2. Data Input

IMPORTANT NOTE

You are obliged to check the correctness of the data input.

2. SAFETY

2.1. General

This chapter contains information which must be considered for safe handling and use of the Excimer laser.

IMPORTANT NOTE

The safety instructions must be strictly followed.

This serves your personal security and the protection of the product from damage.

2.2. Explanation of Safety Alert Symbols

The following conventions are used in this manual:

WARNING!

WARNING alerts of potential serious outcomes to the patient or user.

CAUTION!

CAUTION alerts to exercise special care necessary for the safe and effective use of the device.

IMPORTANT NOTE

Notes provide helpful or supplementary information.

The following symbols are placed to the equipment (identification label):

CE 0483	CE sign. Confirms the observance the Regulation for Medical Devices **MDD 93/42/EEC.**
	Consider accompanying documents
	Application part type **B**

2.3. Laser Classification

The product SCHWIND ESIRIS will be operated with the following lasers:

1. One high performance Excimer laser
2. One fixation laser
3. Two positioning lasers

2.3.1. High-Performance Laser

WARNING!

Laser radiation!

Avoid irradiation of eye or skin by direct or stray radiation.

LASER CLASS 4.

The high-performance laser emits high frequency radiation.

The most important characteristic data of the laser are:

Wave lengths:	193 nm
Pulse energy:	max. 20 mJ
Energy density on cornea:	650 mJ/cm^2

Figure 2: Warning sign 'Laser radiation'

Technical data of the high-performance laser are contained in chapter 4 TECHNICAL DATA.

2.3.2. Positioning Laser

Do not look into the laser beam! The positioning laser belongs to class 1. Their output is below 35 µW. As the beams are aimed from an angle at the eye, an influence on the retina under operating conditions is not possible unless the patient turns the head or eye in the direction of the laser.

Further information to the positioning laser is contained in chapter 3.4 Laser Description.

Technical data of the positioning laser are contained in chapter 4 TECHNICAL DATA.

IMPORTANT NOTE

LASER CLASS 1

2.3.3. Fixation Laser

The output of the fixation laser is below 10 µW. Therefore, it belongs to class 1, which allows an indefinite exposure time of the eye.

Further information to fixation laser is contained in chapter 3.4 Laser Description.

Technical data of the fixation laser are contained in chapter 4 TECHNICAL DATA.

IMPORTANT NOTE

LASER CLASS 1

2.4. Safety Precautions - Prevention of Dangers

2.4.1. General

This section indicates safety precautions and control measures which the **manufacturer** and the **user** of a laser mechanism must meet according to its class.

The purpose of safety precautions and preventive measures is to reduce the possibility of coming in contact with the laser radiation and to avoid other risks.

2.4.2. Safety Notes

For safe laser operation the following NOTES are to be observed:

IMPORTANT NOTES

- After switching ON of the Excimer of laser and during laser operation, pay attention to any errors and warnings which may be indicated on the computer screen. Should you have any questions, please contact an authorized dealer of SCHWIND eye-tech-solutions or the service department of SCHWIND eye-tech-solutions. (Refer to chapter GENERAL INFORMATION – Service Hotline).
- All persons who participate in operations or are present for the purpose of the training, must:
  - be enlightened on potential dangers;
  - wear suitable laser eye protection (refer to chapter 2.4.6.2 Protective Glasses)
- Good room lighting is important in the area where laser eye protection is worn. Bright defused wall surfaces are thereby helpfull.
- The menu structure is interactive. Do not continue if the display screen is dark or if the visibility/representation is reduced.
- Follow the instructions of the trade association VBG 93. Persons not familiar with the laser must be informed about possible risks.

For safety use of the laser system - the following WARNINGS must be followed:

WARNING!

The Excimer Laser system may not be operated in rooms and areas where danger of explosion exists.

WARNING!

Hazard for persons with pacemaker!

Treatment of patients with pacemakers is not allowed.

The presence of persons with pacemakers (treated persons, assisting doctors, nurses and service personnel) in the laser treatment room during laser operations is not allowed.

Potential electromagnetic radiation can interfere with the functioning of pacemakers and can endanger those persons.

WARNING!

Hazard for unborn life.

The treatment of pregnant patients is not allowed.

Potential electromagnetic radiation can endanger pregnant persons.

WARNING!

While handling the accessories or other materials which come into direct contact with the patient, precautionary measures must be met in order to prevent disease transmission.

Exposure of the eye or the skin to direct or scattered laser radiation must be avoided in all cases.

2.4.3. Manufacturer's Responsibility

Manufacturer and dealer are only responsible for proper operation, reliability and security of the device when:

- Transport, installation, initial operation, changes, service and maintenance are exclusively carried out by service personnel authorized by SCHWIND eye-tech-solutions.
- The power connection in the room in which the laser is operated complies with the legal regulations and technical specifications of SCHWIND eye-tech-solutions concerning the installation.
- The device and equipment is operated in accordance with the specifications in this user manual.

2.4.4. Protective Measures of the Manufacturer

The SCHWIND ESIRIS Excimer laser system, as medical laser device, corresponds with the safety requirements of the DIN EN 60601-2-22, "Standard for Medical Lasers" and the DIN EN 60825-1 "General Standard for Laser Security".

The necessity for personal protection measures of the user against dangerous effects from the laser are reduced to a minimum through various measures undertaken by SCHWIND eye-tech-solutions during the manufacturing process of the Excimer of laser.

The most important measures are:

(1) **Technical design of the Excimer of laser with integrated safety features,** such as:

- enclosure of the beam;
- Guard against accompanying radiation;
- Mounting of control equipment and control features on the laser housing so that switching on and operating the equipment can be carried out without danger of the laser beam exceeding radiation units.
- An EMERGENCY STOP SWITCH „Laser Stop" for immediate stopping the laser (refer to chapter 6.6 Control Panel of the Excimer Laser);
- Posting of appropriate warning signs on the equipment against visible and invisible laser radiation (refer to chapter 2.4.4.2 Warning Signs)
- Safety notes in the User Manual
- Appropriate warning references in the laser software which appear on the screen during the laser operation.

(2) **Organizational Measures**, such as:

- Classification of the ESIRIS Laser (refer to chapter 2.3 Laser Classification);
- Training courses for the service personnel (refer to chapter 2.4.4.1 Training of the Service Personnel);
- Start up of the ESIRIS laser system (refer to chapter 5.6 Start-Up).
- Maintenance and service (regular TSC controls) (refer to chapter 9.3 Technical Security Check (TSC))
- Support of the operator and user by the service department of SCHWIND eye-tech-solutions (refer to chapter GENERAL INFORMATION – Technical Assistance);
- Warranty for the laser systems (refer to chapter 1.4 Warranty);
- Providing of equipment documentation consisting of Medical Apparatus Book, User Manual, OP Manual and technical brochure of the SCHWIND Excimer laser.

(3) **Conformity with guidelines of the European advice concerning electromagnetic compatibility (89/336/EEC)** (refer to chapter 2.4.4.5 Conformity with Safety Directives).

2.4.4.1. Training of the Service Personnel

As with any technological highly-developed medical device, the operation of the Excimer laser requires special training and abilities of the service personnel.

IMPORTANT NOTE

The SCHWIND ESIRIS Excimer laser system may only be operated by specially trained physicians or surgeons who have mastered the functions of the laser and who possess the necessary skills, to use it in accordance with the instructions in this User Manual.

The training can be accomplished by the manufacturer SCHWIND eye-tech-solutions or through a SCHWIND eye-tech-solutions authorized representative.

The completion of training for the responsible ESIRIS operators and other persons involved in operation, care, maintenance of the Excimer laser, must be documented in the Medical Apparatus Book. The Medical Apparatus Book is a part of the equipment documentation provided with the Excimer laser ESIRS through SCHWIND eye-tech-solutions.

2.4.4.2. Warning Signs

The laser beam exit is marked with appropriate laser warnings (see Figure 3: Laser warning signs).

LEAVING
FOR LASER RADIATION
VISIBLE AND INVISIBLE
LASER RADIATION
AVOID EYE OR SKIN
EXPOSURE TO DIRECT OR
SCATTERED RADIATION
CLASS IV LASER PRODUCT
Treatmentlaser Positionlaser Fixationlaser
Wavelength 193 nm 633 nm 650 nm
Energy/Power 20 mJ < 100 µW < 10 µW
Energy density 800 mJ/cm²
Pulse duration 8 ns ∞ ∞
Pulse frequency 200 Hz
Laser class 4 2 1
According to EN 60825-1:2001-11

Figure 3: Laser warning signs

The laser warning signs are placed on the protective laser housing near the exit point of the laser beam. (see Figure 4: Warning signs at the laser beam exit).

Figure 4: Warning signs at the laser beam exit

2.4.4.3. Main Key Switch

When not in use, the Excimer laser is to be protected from unauthorized use by removing off the key from the key switch. (Refer to chapter 6.3 Switch ON the Device.)

2.4.4.4. Accessible Beam Area

The beam area of the device runs vertical down from the output opening to the next surface. Normally this is the patient bed or, in case of treatment, the patient's eye. The beam diameter at the output opening is app. 0.9 mm. In the focal plane, which is 280 mm under the output opening, the beam has a diameter of 0,9mm as well. Output and energy density of beam decreases according to increasing distance from treatment area.

2.4.4.5. Conformity with Safety Directives – Electromagnetic Compatibility

The laser system has been tested and its conformity with the limitations of the European Council Directives (89/336/EEC) regarding electromagnetic compatibility has been verified.

2.4.5. Operator's Responsibility

The operator is responsible for:

- Compliance with accident prevention regulations and regulations concerning installation, operation and usage of medical products (Medicine product operator regulation – MPBetreibV). For more information refer to chapter 2.5 Regulations for Medical Devices.
- Usage;
- Proper and secure condition of the product;
- Storage of the user manual near the Excimer laser.
- Inspection of the system at regular intervals.

2.4.6. Protective Measures of the User/Operator

In order to ensure the safety of patients and of the service personnel the user must undertake certain measures as listed in the following chapters:

2.4.6.1. Laser Warning Lamp

- It is possible to connect the warning lamp on the room wall near the entrance door of the laser room.
- Warning lamp must be switched on during laser operation.

Warning lamps will not be delivered, but there is the provision of a 24V relay connection with a warning lamp switch at the electronic box.

2.4.6.2. Protective Glasses

All persons inside the room (except the patient) must wear protective glasses, according to DIN EN 207, when the laser is working. These glasses must have protection level 7 for beams of 193 nm. The operating surgeon may remove the glasses, when he looks through the microscope. The glass optics of the microscope weakens the laser beam so that the necessary protection level is achieved. Protection level of glasses depends on maximum existing central output density (at max. pulse following frequency) or the maximal energy density. These values are 5×10^2 J/m^2.

2.4.6.3. Protective Clothing

(Only for pulsing high-performance Exciter laser)

Exposure of the skin to direct or indirect radiation has to be avoided. This is achieved e.g. via wearing of a suitable work clothing.

2.4.6.4. Mirrored Reflection

Ensure that there are no reflective objects in the area of the laser beam, because this may lead to dangerous mirrored reflections.

2.4.6.5. Installation Requirements and Environmental Conditions

Information regarding room, installation requirements and climatic conditions which the user has to fulfil can be found in the chapter 5.5, Room and Installation Requirements.

2.5. Regulations for Medical Devices

The laser system of SCHWIND eye-tech-solutions belongs to laser class 4. It is the class with the highest danger potential.

IMPORTANT NOTE

For a safe use of the laser class 4 and as medical device of class IIb the **operator** must consider the applicable, normative regulations and directives.

The most important of these are:

1. **Regulation for Accident Prevention „BGV B2 Laser Radiation“**
   (Previous name VBG 93 dated 1. April 1988 in the version dated 1. January 1993)
   (Regulation valid only for Germany; Please consider the valid national regulations)

2. **Council Directives concerning Medical Devices MDD 93/42/EEC**
   (Regulation valid for EEC countries; Please consider the valid national regulations)

3. **Medical Product Operator Regulation – MPBetreibV**
   (Regulation valid only for Germany; Please consider the valid national regulations)

4. **BGV-A2 Safety Examination of Electrical Devices**
   (In the past: VBG4)
   (Regulation valid only for Germany; Please consider the valid national regulations)

2.6. Dangers Resulting from Laser Operation

2.6.1. Laser Radiation

Radiation from high-performance lasers is potentially dangerous. In our case, however, danger is minimized by the following effects as listed below:

- The beam diverges after passing the ablation area, so a high energy density exists only in that area.
- The beam is partially absorbed in the air.
- The cornea does not reflect the laser beam during treatment (any reflection is only a very weak beam).

These effects reduce the energy density of the beam quickly with increasing distance to the working area, which is about 280 mm under the beam output opening.

2.6.2. Working Gas

Danger from the working gas (neon 96.56%/argon 3.33%/fluoride-gasmixture 0,11%) is minimal because of the low fluoride concentration (approx. 0,11%) and general protection (e.g. the neutralization filter in the gas containment compartment).

During the exchange of the operating gas of the laser tube the old gas is neutralized by a filter and becomes harmless thereby.

The laser head contains only a small quantity of fluoride. It is checked according to the pressure containment regulations. An unintentional output of working gas is very unlikely. Fluoride can be recognized through its pungent smell long before the concentration will reach maximum allowed values for work areas. If a fluoride gas leak is detected, open the window, leave the room and call the service department of SCHWIND eye-tech-solutions or the service of your nearest distributor.

2.6.3. Pressure Gas Bottle - Gas Containment:

The pressure gas bottle with working gas is stored inside a gas containment compartment. This gas containment compartment is airtight and has a filter which will absorb the fluoride if there is a leak. A pressure gas bottle containing helium, used for service demands, is also stored inside the gas containment compartment.

2.6.4. Electrical Safety

2.6.4.1. Connection of Devices to External Plugs

To ensure electrical safety, only devices intended for use by SCHWIND eye-tech-solutions (printer, monitor, etc.) may be connected to the external plugs (see also chapter 3.10 Accessories, Consumables, Disposables).

Additional devices connected to analogy and digital plugs of the system must fulfil EN specifications (i.e. EN 60950 for data processing devices or EN 60601-1 for electrical medical devices).

IMPORTANT NOTE

Persons connecting additional devices to signal input or output are reconfiguring the system and are responsible for ensuring that the specifications outlined in EN 60601-1 are maintained.

Should you have further questions, please do not hesitate to contact the Service Department of SCHWIND eye-tech-solutions.

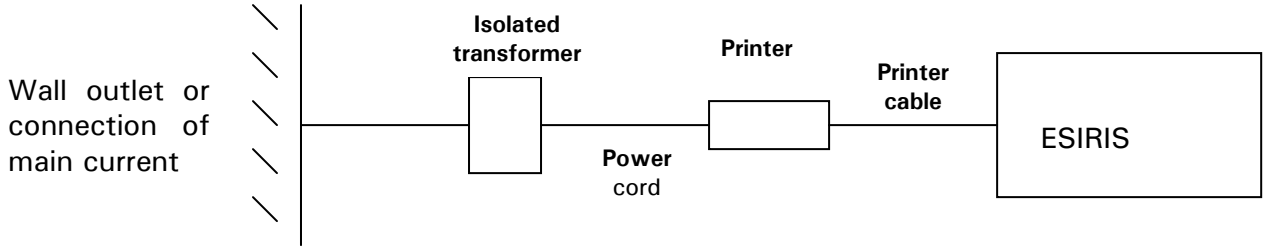


Figure 5: Sample of printer connection

2.7. In Case of Emergency

In chapter 2.6 Dangers Resulting from Laser Operation, dangers were listed which could occur during laser operation. The risk of an emergency is lowered to a minimum by the technical design of the system and the organizational measures taken by the manufacturer (refer to chapter 2.4.4 Protective Measures of the Manufacturer).

If a danger for the service personnel and the patient during the laser operation should arise despite the protective measures of the manufacturer, the following steps have to be taken:

(1) Gas leak (laser operating gas)

- Open the windows,
- Shut down the laser system and switch off the device using the emergency stop switch, if time permits it (refer to chapter 6.6 Control Panel of the Excimer Laser),
- All personnel must leave the room,
- Inform the service department of SCHWIND eye-tech-solutions or the customer service of your distributor (see Service Hotline).

(2) Other dangerous situations

- Switch off the laser system using the emergency stop switch,
- Bring the patients and the service personnel to safety,
- Inform the service department of SCHWIND eye-tech-solutions or the customer service of your distributor (see Service Hotline).

(3) Accidents because of laser radiation

In the case that persons receive injuries to the eye or skin from laser radiation, a thorough examination must be performed by a medical professional. Observe the requirements of Norm EN 60825-I.

An accident notice is to be submitted to the responsible supervisory authority. A copy of this message has to be sent to SCHWIND eye-tech-solutions GmbH & CO. KG. You will find a sample of the damage report in your Medical Apparatus Book in chapter 8.

(4) Accident situation

In the case of a work accident, resulting in injury of a patient or the service personnel, after carrying out any medical care, an accident notice is to be submitted to the responsible supervisory authority. A copy of this message is to be sent to SCHWIND eye-tech-solutions GmbH & CO. KG. You will find a sample of the damage report in your Medical Apparatus Book in chapter 8.

3. SYSTEM DESCRIPTION

3.1. General

This chapter gives an overview of the ESIRIS components and describes in short form the main function units of the ESIRIS, the operation and control elements and the available accessories.

3.2. System Overview

The SCHWIND ESIRIS Excimer Laser System consists of the following components:

1. The optical system, which consists of:
   - Optical Arm
   - Scanner
   - Positioning laser
   - Fixation laser
   - Camera
   - Microscope
   - Infrared illumination
   - Laser
2. Control-PC with Eye-Tracker-card
   - Monitor
   - USB-Stick
   - Touch pad with plug socket for USB
   - Keyboard with track ball
3. Electronic-box
4. Gas-containment
5. Patient bed
6. Compressor (for air rinsing) or
7. Equipment for nitrogen rinsing
8. USV

The following components are optional:

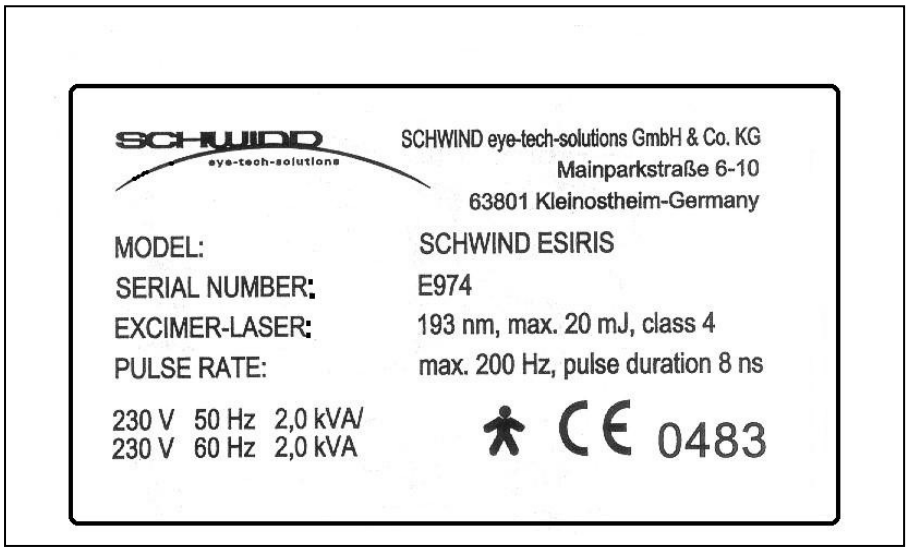
1. Video adapter for camera
2. ORK-link (Optimized Refractive Keratectomy = ORK)
3. Printer
4. One to one transformer

3.3. Unit Labelling

The ESIRIS is labelled according IEC 825-1 (EU-Version).

3.3.1. Identification Label of the Device

The identification labels of the manufacturer are placed below the device tower (visible) as well as on the beam delivery system of the ESIRIS and on the Z-tower of the patient bed (not visible).



Application part:
Type B

Figure 6: Identification label of the laser

3.4. Laser Description

3.4.1. Excimer Laser

The high-performance Excimer laser is designed for the ablation of human eye tissue.

3.4.1.1. The Main Principle of the Laser

Excimer gas lasers are stimulated with an electric pulse in a mixture of noble gases and halogens. The output lifts the noble gas atoms to a higher energy level so that they react with the halogen molecules and bond to them, as ArF.

These special molecules, known as excimers (excited dimers), are stable only for a short time. They collapse and emit a high ultraviolet beam. If the gas is arranged in an optical resonator of two parallel mirrors, the laser effect is achieved and light impulses with very high outputs are beamed.

The laser gas consumes itself partially during the output and must be changed after 10 x 10^6 impulses or after 2-3 days.

The OPTEX laser used with the ESIRIS is produced by Lambda Physik, Goettingen. It is a very compact unit optimized for reliability and low gas consumption.

The performance data listed in chapter 4, TECHNICAL DATA, prescribe the data of the laser and the necessary voltage connections.

The laser source is laid out for a treatment mode in which the laser pulses for max. 5 minutes (treatment) and 5 minutes in “standby” mode (OP- preparation before and after treatment) remains.

Figure 7: Optex-Laser

Besides the high-performance laser of the ESIRIS, three low-power diode lasers are also used. They are two positioning lasers and fixation laser.

3.4.2. Positioning Laser

The two positioning lasers are used to adjust the exact working distance from the corneal surface.

The two beams of the positioning laser will be displayed on a surface as two red points.

3.4.3. Fixation Laser

The fixation laser is used for fixation of the patient eye.

The fixation laser beam of laser system with patient bed type "I" is displayed on a surface as a red, blinking point.

The fixation laser beam of laser system with patient bed type "II" is displayed on a surface as a green, blinking point.

3.5. Gas Supply

The noble gas mixture must be ordered directly at SCHWIND eye-tech solutions or the responsible SCHWIND dealer to guarantee purity levels and strict check criteria. Otherwise damage to the system can occur. This is part of the Service and Maintenance Agreement.

A gas change should be carried out once a week (also if the laser is not in operation). This supports and achieves the productivity of the laser. Additional information regarding the gas change – refer to chapter 7.4 Gas Exchange - Excimer Laser.

The gas bottle must be changed by a SCHWIND eye-tech solutions service engineer/technician or a trained service technician of a SCHWIND dealer.

IMPORTANT NOTE

Failure to follow these instructions will invalidate any guarantee or claim of responsibility by SCHWIND eye-tech solutions

CAUTION!

Damage of device!

In case the SCHWIND ESIRIS Excimer laser system is not in operation for a period over 3 months, please contact the Service Department of SCHWIND eye-tech-solutions.

3.5.1. Gas Containment:

The Laser operates with pre-mixed „PREMIX“ gas. The capacity of one bottle is sufficient for about 130 filling at standard operation (approx. 12 months under normal working conditions).

3.6. The Optical System

The optical system for beam guidance and forming is flanged connected to the laser at its output with a protective tube. The beam is turned four times at a 90° angle each time. Output of the treatment is perpendicular to the treatment area, coming down axially with the optical axis of the video control system and of the fixation laser, which are used for centralization.

The treatment area is about 280 mm under the beam output housing. Focusing of ablation field and centering on the eye is performed with two positioning lasers, a video camera and a microscope. A video picture with crosshair is produced on the monitor, which allows easy centering of the pupil.

The maximum ablation field in the focus level has a diameter of max. 14.0 mm.

Two diode lasers with low energy are used as positioning lasers. They are directed punctually at the eye at an angle from left and right so that the points cross at the exact distance of focus and the center of the ablation area.

A fixation laser beams through the optical axis of the unit onto the eye and is used as a fixation target for the patient. The laser power is below 10 µW, which allows prolonged illumination of the eye without causing any damage.

3.6.1. Rinsing of Optical Beam Delivery System

Radiation of an ArF Excimer laser is 193 nm, which is at the outer limit of the ultra violet light spectrum through which air is transmitted. Partial absorption through air (oxygen) noticeably decreases the radiation and ozone is produced. This would damage the optical components if it were allowed to accumulate inside the delivery system. For this reason, it is necessary to flush the beam path.

There are two different methods that may be employed to flush the beam path of the ESIRIS laser:

- Air flushing by way of an air compressor

Or

- Nitrogen flushing by way of a pressurized bottle.

With air flushing, the compressor takes in surrounding air from the environment, filters it and flushes it through the beam delivery system.

Nitrogen flushing is accommodated by a pressurized bottle and a gas flow regulator with a preset flow of 8 l/min [litre per minute].

3.7. Microscope and Illumination

A coaxial stereo microscope is used for exact control and focusing of corneal surface. It allows coaxial stereoscopic control of the eye without the control beam path being guided through the working optic of the device. Therefore, a very high quality picture is possible.

Abrasion of the epithelium and LASIK can be performed under optimal control conditions. Furthermore, the control of treatment results is possible.

The cross hair is only constructed for a magnification of 10x (at 5 step changer) and for a magnification of 8x (at 3 step changer)!

Any another magnification could result in a shift of the crosshair. Further function description of an operation microscope is given in chapter 6.7 Operating of the Microscope.

For illumination of treatment area, a cold-light lamp or a LED illumination (see Figure 8: LED illumination) is integrated into the unit. This lamp can be adjusted in brightness and switched off with a potentiometer if necessary. The light is provided directly from the ends of fibreglass (fibre-optic) cables which are located in a ring-formed output below the beam output lens.

Figure 8: LED illumination

3.7.1. Major Components

The major components of the operating microscope are:

- Manual 5 step magnification changer (6)

Or

- Manual 3 step magnification changer (6)
- 0° to 75° microscope eyepiece head (1)

3.7.2. Magnification Changer 5 Step or 3 Step

The 5 step or 3 step magnification changer (6), is operated manually.

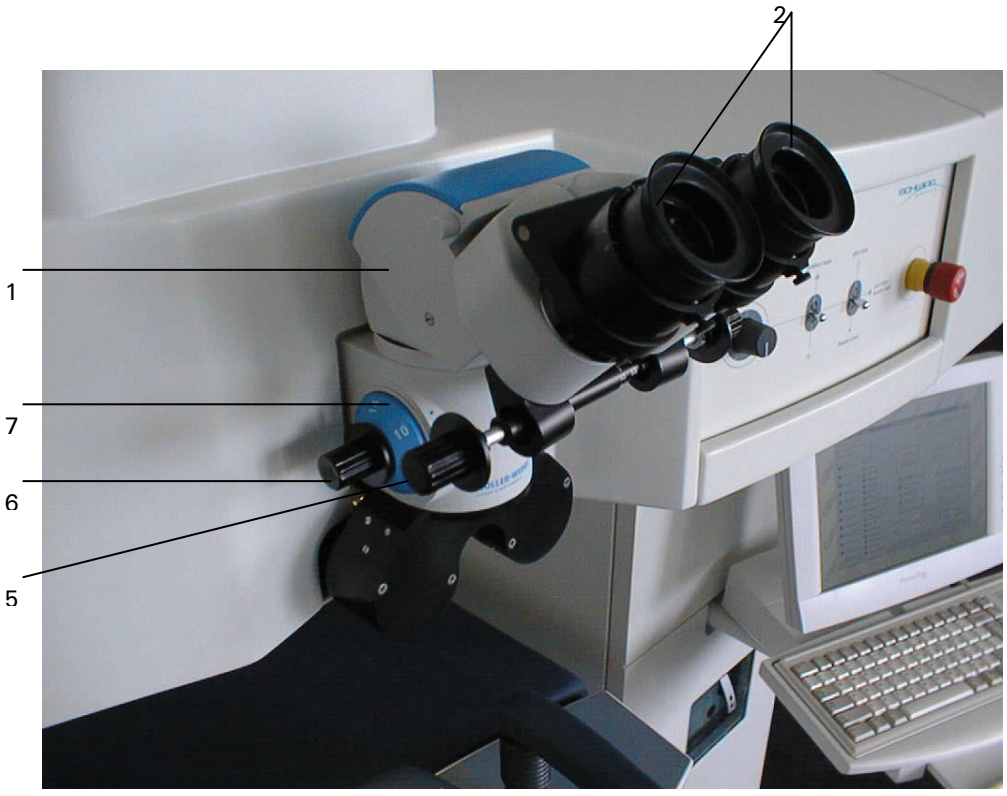
- The selected magnification (7) is shown on the turning knob.

3.7.3. Microscope Eyepiece Head

As a standard, the operating microscope is equipped with a 0° to 75° eyepiece head (1).

Each ocular (2) provides dioptre setting of +5 to -8 D which can be adapted to the ametropia of the user. For better observation spectacle wearers should push in the setting rings (3).

The pupillary distance (PD) can be set via a spindle (5) from 50 to 75 mm. Adjust the PD such that the image is observed by both eyes.



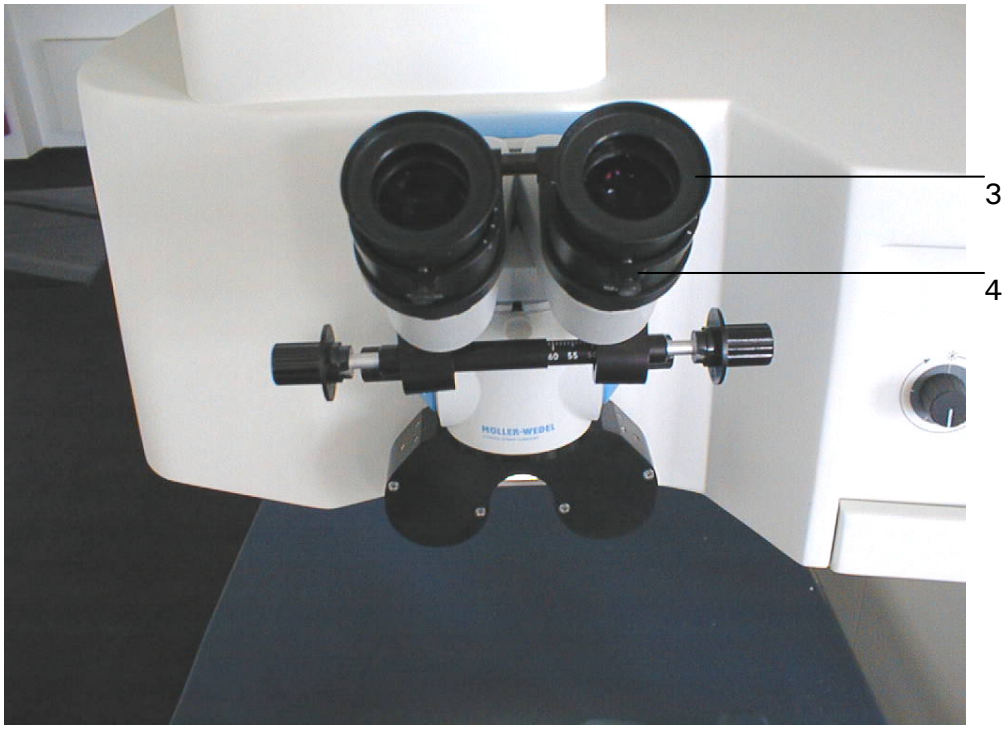


Figure 9: Components of the operation microscope

3.8. Foot Switch

The foot switch is used to start the treatment or test procedures. This switch has two switch points to avoid unintentional release of pulses. The treatment procedure can be interrupted any time by releasing the foot switch. The program remains active, so the treatment can be continued at any time by pressing the foot switch again.

3.9. Patient Bed

3.9.1. Conventional Use

The patient bed is intended specifically for ophthalmologic purposes and is optimal for treatments with the ESIRIS Excimer Laser.

The patient bed easily facilitates precise and stable positioning of the patient, as well adjustment to the treated eye at the ablation area.

Any use other than that outlined in this User Manual lies within the exclusive responsibility of the user.

3.9.2. Patient bed Type „II“

With the ESIRIS patient bed Type “II” has been set a new standard in terms of functionality and design.

Figure 10: ESIRIS patient bed Type “II”

Standard equipment:

Corpus: powder coated with 2 colours (RAL 9002 light grey / RAL 5011 steel blue).

Upholstery: abrasion – resistant, air permeable material, colour midnight blue with additional plastic cover to protect the foot area.

Headrest: adjustable – very stable.

Figure 11: Patient bed – headrest

3.9.3. Operation Instructions

The correct operation of the patient bed guarantees a safe service life of the device. Please become intimately familiar with the following information regarding operation of the patient bed in chapter 6.8 and chapter 6.9.

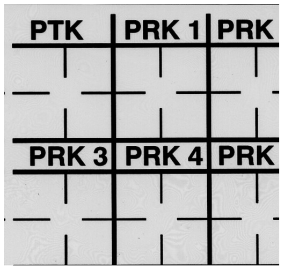
- The patient bed should not be installed in damp rooms. Avoid dripping, standing, or splashing water near the device.
- Installation, modifications, and service of the patient bed may only be performed by authorized personnel.
- The operation of the patient bed in an explosion area is not allowed.

3.10. Accessories, Consumables, Disposables

3.10.1. Accessories

Description	***Article Number***
Video-colour camera system (Complete system with camera, electronics, holder, cables)	
C-Mount Adapter	10397
Beam splitter	10396
Panasonic CCD-Video camera with digital signal processing	9297
Controller-unit for Panasonic-video camera	9298
Power pack12V for video camera	8975
Panasonic C-mount adapter	8976
Printer: Windows- compatible Printer inkjet printer HP DeskJet for connection to parallel interface (for use with a one-to-one transformer only)	11955
One-to-one transformer: For external connection of a printer	1 2201
ESIRIS Data base Main licence Secondary licence	 12197 12198

3.10.2. Consumables

Description	***Article Number***
HS-Foil for Fluence-Test: High Stability Foil (clear, transparent plastic foil)	12066
PMMA-Measurement plates: 20x60 mm, thickness: 2mm 	8956
Photo paper For drift measurement	11715
Spare halogen lamp 12V / 75 W	11195
Assisting gas Helium, 10l Gas bottle	L 602
Operation gas - Laser PREMIX-Gas; 20 l Gas bottle	11669

4. TECHNICAL DATA

4.1. General

In chapter TECHNICAL DATA you will find all technical data of the ESIRIS.

4.2. Laser System

Working Laser	**ArF-Excimer-Laser**
Laser class	4
Wavelength	193 nm
Power (middle, beam output)	4 W max.
Mode	pulsed
Pulse energy (beam output)	20 mJ max.
Pulse frequency	200 Hz max.
Pulse duration	8 ns
Pulse-to-pulse stability	< 5 %
Power density (treatment area)	$<1{,}3 \times 10^6$ W/m^2
Energy density on cornea (treatment area)	650 mJ/cm^2
Beam diameter (output)	7 x 4 mm
Treatment area	app. 280 mm under beam output
Beam diameter (treatment area)	0.8 mm FWHM (Full Width Half Maximum)
Beam divergence	2 x 1 mrad

Positioning Laser (Pilot laser)	**Diode Laser**
Laser class	1
Wavelength	635 nm
Power (middle, beam output)	< 35 µW
Mode	continuous

Fixation Laser	**Diode Laser**
Laser class	1
Wave length	red = 650 nm or green = 532 nm (starting from serial no. 151)

Power (middle, beam output)	< 10 µW
Mode	continuous

Performance Data of the Laser

Power supply voltage:	230 V AC +/-10 %, 1 Phase
Frequency:	50 Hz or 60 Hz
Power Input:	1.5 kVA
Fused phase protection:	6.3 A
Device connections	acc. to IEC standard

Control System	**Industry PC 586AT (or better)**
Hard Disc	13.6 GB (or more)
Processor	Pentium III 500 MHz or higher
Memory	64 MB
Monitor	12.1'', VGA flat monitor
Interlock	1 opener external
Monitor output	VGA socket

Cooling	**Air**
Cooling Circulation	internal fan

Input Requirements

Electrical connection:	1.2 kVA
Power supply voltage:	1 Phase, 230 V +/- 10%
Power:	16 A, slow phase
Frequency:	50/60 Hz
Connections:	CEKON (blue) wall socket 230V/16A/3-pol

Dimensions and Weight

Floor Space	refer to chapter 5 INSTALLATION
Total weight	app.640 kg
(Incl. patient bed & 2 gas bottles)	

Floor Requirements

Laser system and beam delivery system:	250 kg
Point weight through supporting	
Feet at the laser:	max. 75 kg
Base of supporting feet:	app. 28 cm² per support
Patient bed:	180 kg
No. of laser supporting feet:	4
No. of supporting feet for the patient bed:	4

Patient Bed type "II"

All dimensions are approximately values	
Total length	1895 mm
Length of pad	1680 mm
Total width	640 mm
Lift/lower adjustable range	150 mm
Lift/lower rate until	10 mm/s
Adjustable range left / right	100 mm
Left-right speed to	6-7 mm/s
Adjustable range forward / backward	300 mm
Forward / backward rate until	6-7 mm/s
Short term operation 10 minutes	50%
Power supply	230 V 50 Hz
Power input	230 VA
Fuse F1	2xT 4 A 250 V
Weight	180 kg

Eye-Tracker Camera

Frequency	240 Hz or 328 Hz

EU-Labelling

CE 0483 marking

Medical Device Class 2b acc.

MDD 93/42/EEC Application part: Type B

5. INSTALLATION

5.1. General

This chapter describes the delivery, unpacking and the installation of the ESIRIS.

Installation of the ESIRIS is performed by trained service personnel of the SCHWIND eye-tech-solutions. To ensure a proper installation, some requirements must be met as described in chapter 5.5 Room and Installation Requirements.

5.2. Shipping

5.2.1. Packing of the Shipping Units

The complete shipping unit consists of the laser, optical system, patient bed PC and monitor, the device housing as well as accessories and consumables (refer to chapter 3.2 System Overview).

The several components of the ESIRIS will be packed separately and can be shipped by air, by forwarding agency or as direct delivery.

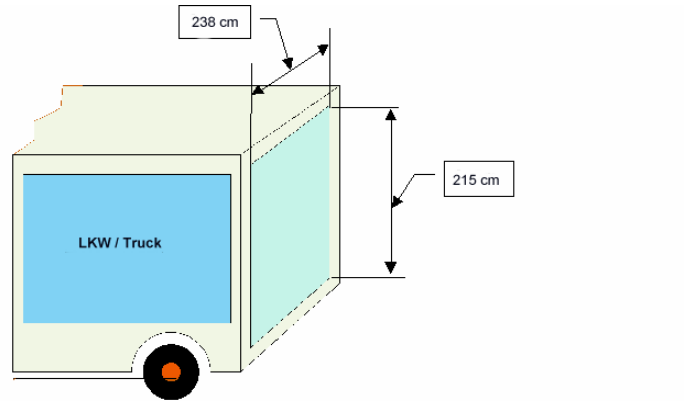
The delivery by air or by forwarding agency consists of three wooden boxes with the following dimensions:

Box 1: 150 x 110 x 175cm gross weight: 424 kg (Laser + attachments)

Box 2: 220 x 110 x 125 cm gross weight: 406 kg (bed + attachments)

Box 3: 180 x 105 x 115 cm gross weight: 295 kg (covers + cases)

The direct delivery will be carried out by a small lorry (see Figure 12: Truck dimensions).



For the delivery by forwarding agency a truck with a minimum height of 2,15 m and inside dimensions of 2,38 m, with a min. length of 3.50 m is necessary.

Figure 12: Truck dimensions

5.3. Unpacking and Checking the Crates

(1) After delivery of the device units, check immediately for outside damages to the boxes and its completeness according to delivery list.

(2) Checking and inspection of the device and its components for damage and completeness will be carried out by a service technician of SCHWIND eye-tech-solutions.

(3) If the device or its parts have to be sent back to the manufacturer, please use the original packing.

(4) Outside storage of the boxes must be avoided.

IMPORTANT NOTE

The customer is not authorized to unpack the boxes.

A service technician of SCHWIND eye-tech-solutions or other trained person has to be present during opening of the boxes.

After delivery of the device, inform SCHWIND eye-tech-solutions in Kleinostheim or your responsible Representative in order to organize the installation by our service technicians/engineers.

The customer is not allowed to perform the electrical connection of the device or start installation. The guarantee would expire.

Store the boxes indoors until installation.

5.3.1. Transportation Damages

The packing boxes have been especially designed for best protection of the contents.

The device has been packed properly and in perfect condition at the factory after conclusion of all examinations. Transportation damages are the responsibility of the transporting agent. If any damages are discovered during or after delivery, please proceed as follows:

(1) In case of outer damage, transporting agent has to be informed, to check damage and record it on the delivery note.

(2) In any case of damage call SCHWIND eye-tech-solutions or responsible representative immediately to prepare a report with cost estimation for the insurance.

(3) Store packing material until all questions with transport agent and insurance company are cleared.

5.4. Dimensions ESIRIS

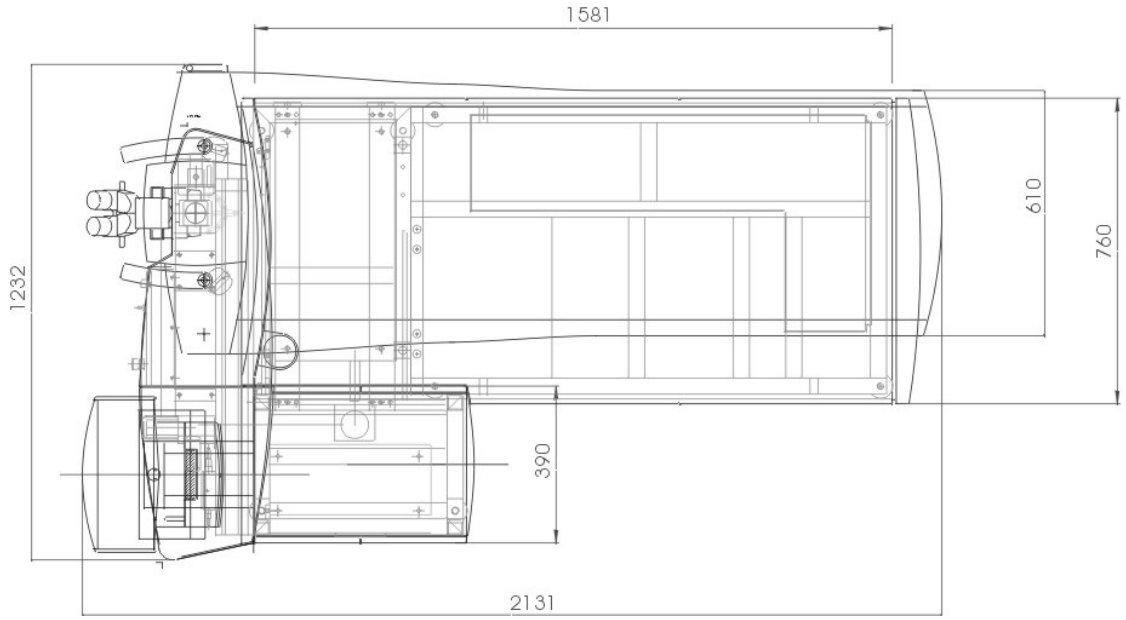


Figure 13: ESIRIS top view

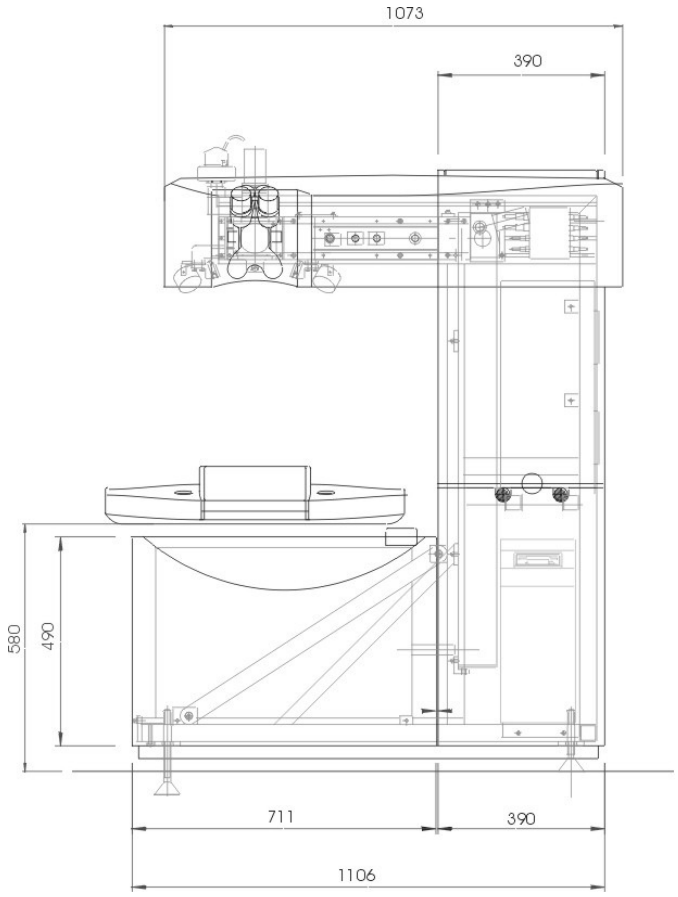


Figure 14: ESIRIS front view

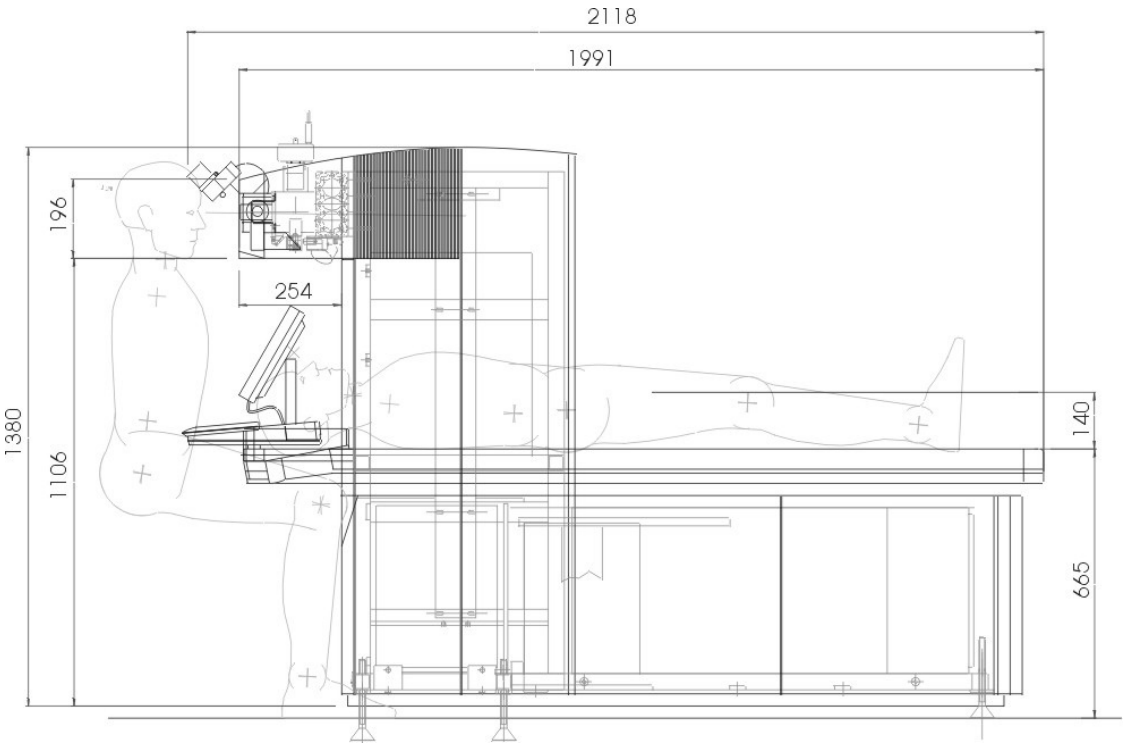


Figure 15: ESIRIS side view

5.4.1. Arrangement of the ESIRIS Feet

All dimensions in mm, drawing size 1:25.

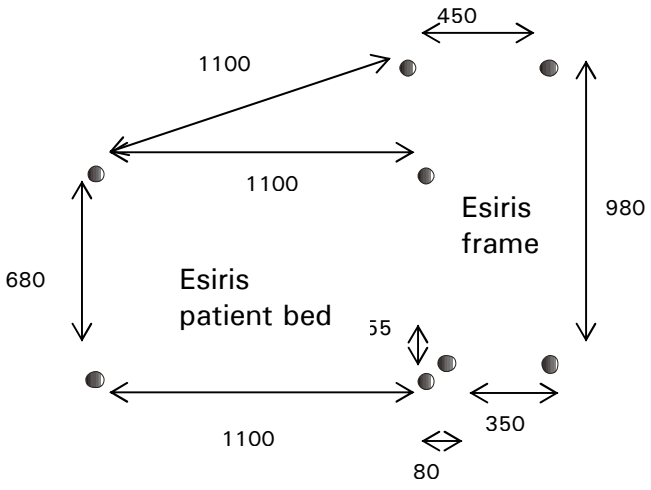


Figure 16: Arrangement of ESIRIS feet

Regarding room requirements for ESIRIS or further technical requirements – please see a separate document **"Requirement Form -Customer Specific System Configuration for ESIRIS"** which you will receive from SCHWIND eye-tech-solutions.

5.5. Room and Installation Requirements

5.5.1. Room Dimensions

The room for installation of the Excimer laser ESIRIS should have a minimum size of 3 x 4m (12 m²). However it will be recommended a room size of 3 x 4,5m (13,5 m²).

All drawing dimensions are indicated mm.

Drawing size 1:50

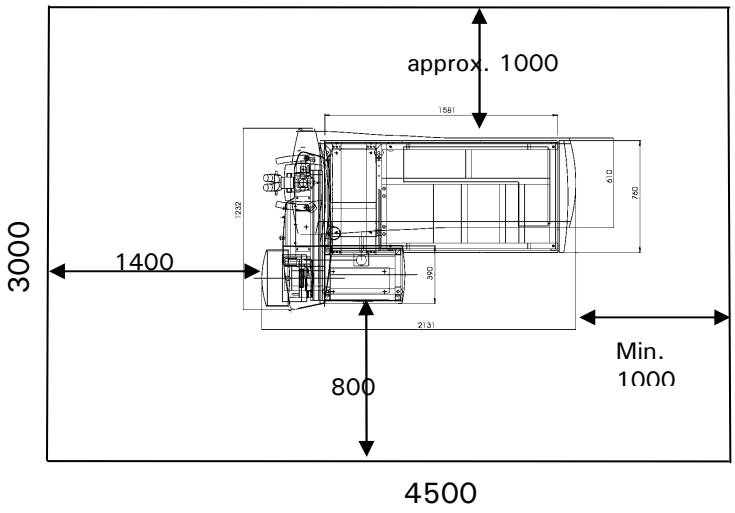


Figure 17: Top view with room dimensions

5.5.2. Room Requirements

(1) Avoid direct solar radiation.

(2) Darkening curtain.

(3) Air conditioning in countries with temperatures of more than 25° C or differences of more than ± 10 %.

(4) Air humidity: 40% (ideal), range: 30% - 50%

(5) Air dehumidifier is absolutely necessary in countries with a humidity of more than 50 %.

(6) On the outer side of the entrance door, a laser warning lamp and the official laser warning symbol must be installed.

(7) A switch which interrupts the laser if the door is opened can be connected through the interlock input at the system. This is only recommended, however, when it is guaranteed, that the door is not opened during treatment.

(8) According to DIN EN 207 protective glasses have to be available in sufficient quantity near the entrance door.

(9) Door width: min. 80 cm

(10) Floor covering: PVC or stable, vibration free underground (no carpet)

CAUTION / WARNING

Damage of device! / Danger to life!

Explosive or inflammable material has not to be stored inside the laser room.

This may lead to explosions endangering persons and equipment.

5.5.3. Installation Requirements

The most important installation requirements are:

(1) An UPS system (uninterruptible power supply) is necessary (included in delivery range of the ESIRIS).

(2) Nitrogen rinsing:

- Nitrogen provision:
  50 l bottle – quality 5,0 (99.999 % N2) min; otherwise the system could be damaged.
- Pressure reducer valve:
  At nitrogen bottle with flow control and adjustable flow of 5-10 l per minute (included in delivery of the ESIRIS) adjusted to 8 l/min flow

Or

(3) Air rinsing:

- Compressor (included in delivery).

Nitrogen gas bottle necessary for use of the laser may be stored inside the laser room.

The N2 bottles must be must be wall mounted beside or behind the laser and secured, to avoid tilting and prevent them from falling down.

5.5.3.1. Input Requirements

For the required performance data of power supply for SCHWIND ESIRIS, please see the data in chapter 4 TECHNICAL DATA.

5.6. Start-Up

Unpacking, installation (start-up) and instruction according to MPG will be performed by a service technician/engineer of SCHWIND eye-tech solutions or authorized Representative.

The service technician inspects the room for necessary installations (dimensions, electrical connection, security regulations and air-condition refer to chapter 5.5 Room and Installation Requirements).

He confirms the correspondence at the inspection protocol and connects the system to the power supply. After a system check and necessary adjustments, he performs operational tests.

IMPORTANT NOTE

Unauthorized starting of installation or use of the device invalidates the warranty

IMPORTANT NOTE

The device must not be transported to another room and be installed and started there without knowledge of SCHWIND eye-tech-solutions or the distributor. In such a case the guarantee would also expire.

6. DEVICE CONTROL AND OPERATION

6.1. General

This chapter defines you the function of each components of the Excimer Laser.

IMPORTANT NOTE

Before operating the Excimer Laser, make yourselves familiar with the safety regulation (refer to chapter 2.4 Safety Precautions - Prevention of Dangers). This serves your personal security and the protection of the product from damage.

The SCHWIND ESIRIS Excimer laser system is allowed to be used by a trained medical professional only.

6.2. Control System

The control system is located inside the device tower beside the patient bed. It includes all voltage delivery units, fuses, and the control computer. Monitor and keyboard are located at the front wall of the ESIRIS.

You can easily interact with the ESIRIS through the keyboard and monitor. Inputs into the computer are menu controlled so that input mistakes can be easily avoided. Release of treatment procedure is accomplished by pressing the foot switch.

6.3. Switch ON the Device

IMPORTANT NOTE

The device is switched on with the Main Switch ON.

The main switch is located at the right side of the device tower.

Based on technical reasons, the unit needs a warm up phase of 5 minutes after starting before the laser can be used. If you try to start a treatment or a Fluence Test within this time, a message will appear: '**Laser still warming up**'.

6.4. Switch OFF the Device

The system can be switched **OFF** as soon as the Windows software is shut down and the screen is black or shows the message **'No incoming signal'.**

Switch the device OFF with the Main Switch.

IMPORTANT NOTE

To avoid unauthorized use of the ESIRIS device, please remove the key from the main key switch when the ESIRIS is not in operation.

6.5. Disconnection from the Electronic Circuit

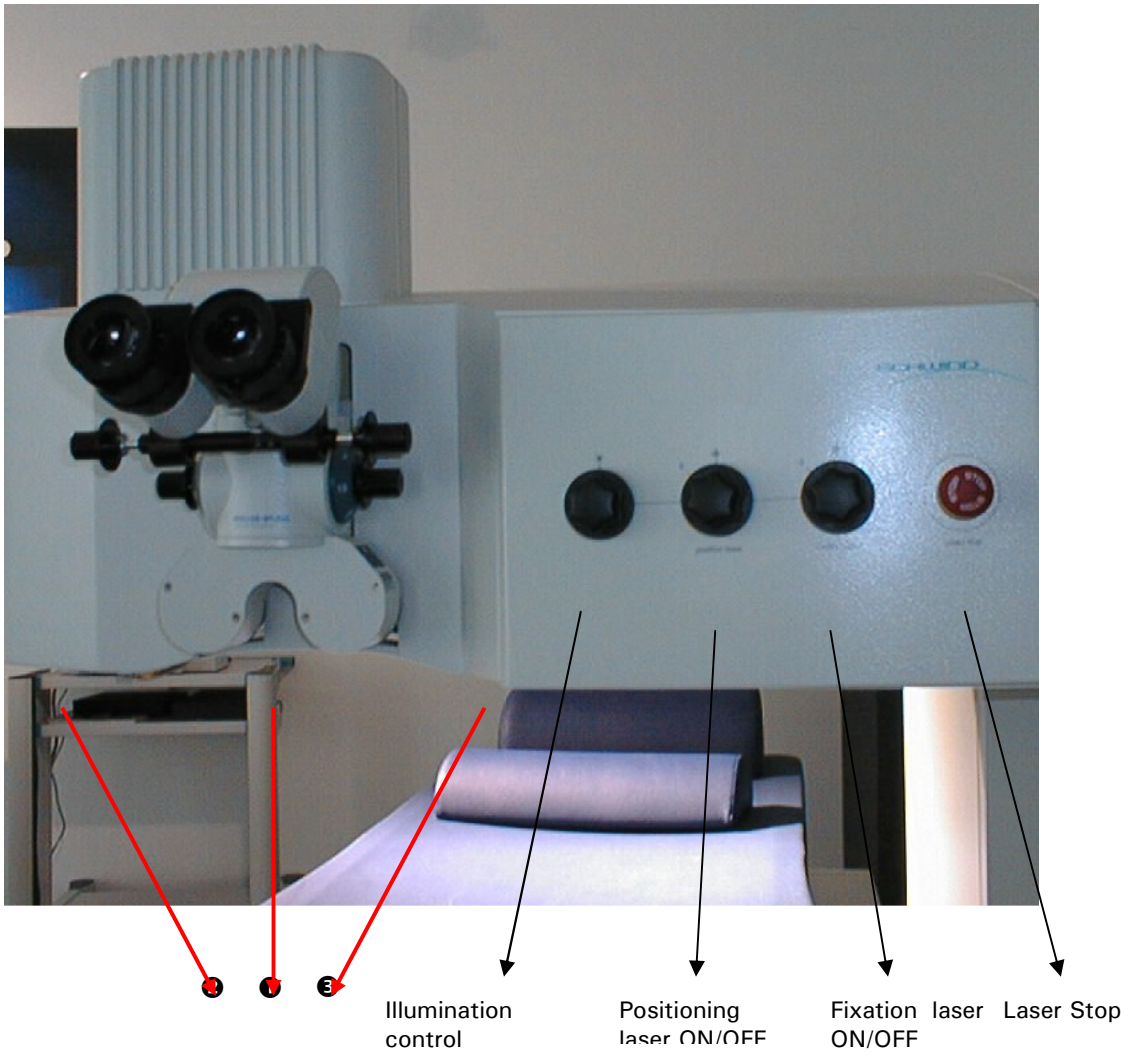
Complete separation from the electronic circuit is only possible through:

- Disconnection of the CEKON plug at the ESIRIS device, or
- Switching off of the uninterruptible power supply (UPS)

IMPORTANT NOTE

Switching OFF of the uninterruptible power supply (UPS) is only allowed by a Service Technician from SCHWIND eye-tech-solution or an authorized representative.

6.6. Control Panel of the Excimer Laser



❶ Beam path of the fixation laser

❷ + ❸ Beam path of the positioning laser

Figure 18: Control panel and laser sources

Explanation of control elements:

Illumination Control:	The OP field lighting can be individually adjusted and turned off by turning the knob.
Positioning Laser:	On/Off switch for the two lasers used for height adjustment. At the correct ablation height, both laser spots overlap exactly into one laser spot.
Fixation Laser:	On/Off switch for the patient fixation target. The patient eye is offered a target to align on as a "rest position."
Laser Stop:	**EMERGENCY STOP SWITCH** for immediate stopping of the laser. The control system is not switched off, however, so that no data loss takes place.

WARNING!

Danger of exposure!

The handling and operation of the ESIRIS device and control features in any other way as described in this User Manual may cause dangerous exposure!

6.7. Operating of the Microscope

6.7.1. Microscope Eyepiece Head

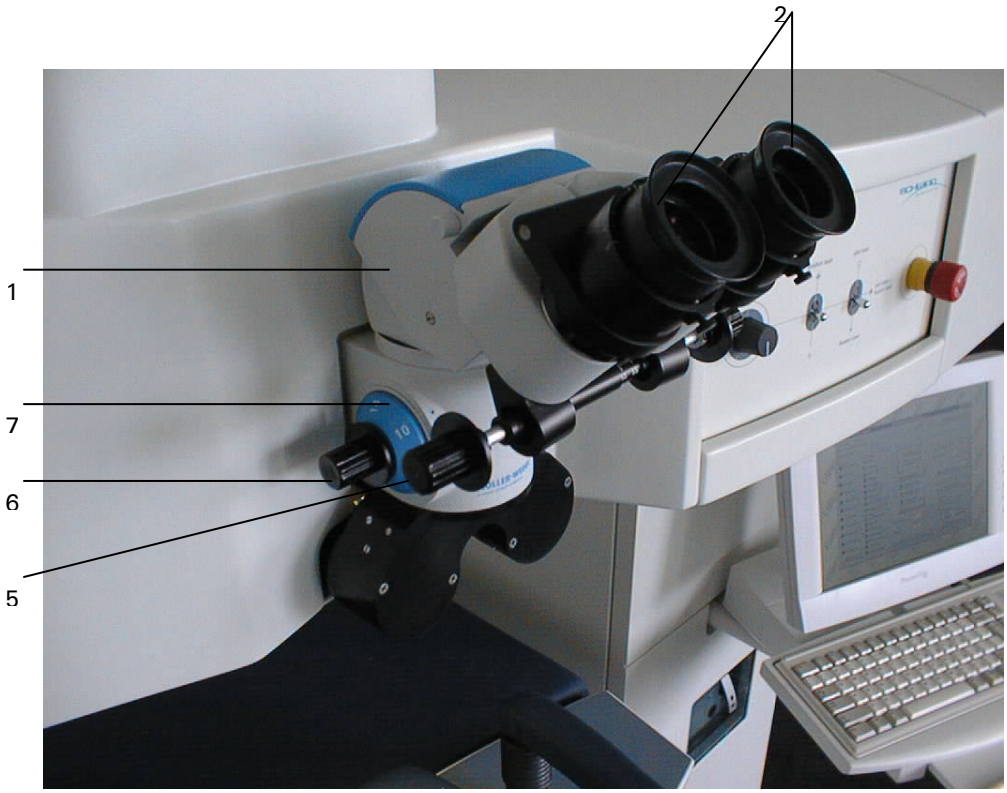
- Spectacle wearers loosen the screw (4), push in the setting rings (3), and tighten again the screw (4).
- Setting of pupillary distance (PD): Via spindle (5) the PD can be set from 50 to 75 mm. While setting the PD, the reticle remains aligned.
- Adjustment of oculars (2) (for persons with deficient vision not using their spectacles): Turn the oculars (2) to the required dioptre value.
- Adjustment of oculars (2) (for normal sighted persons and persons with deficient vision using their spectacles): Turn the oculars (2) to zero.

6.7.2. Focusing

- Set the magnification changer (6) to the smallest magnification (7).
- Focus the object by matching the height of the operating table.
- Set the magnification changer (6) to the largest magnification.
- Re-focus.
- Set the required magnification.
- The selected magnification:
- 5 step changer (5x, 7x, 10x, 14x, 20x)

or

- 3 step changer (4,5x, 6x, 8x) can be read on the turning knob (3).



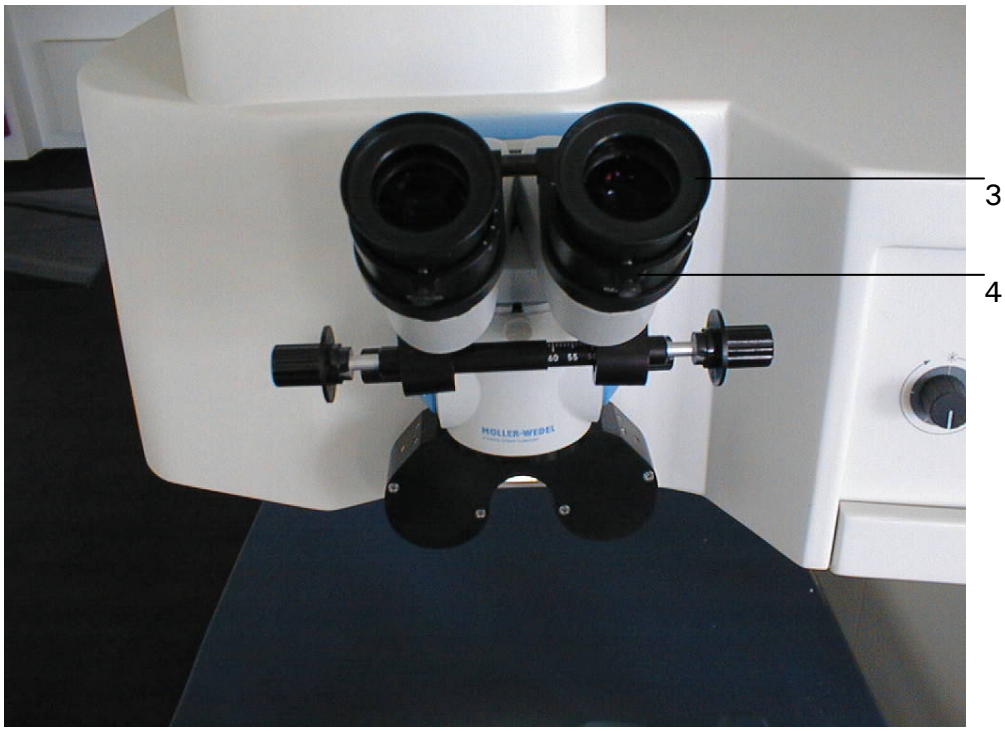


Figure 19: Components of the operation microscope

IMPORTANT NOTE

While changing the magnification, the image will remain sharp. In case of smaller magnification, the depth of field will increase.

6.8. Patient Bed Control Type "I"

6.8.1. General

The patient bed type "I" is designed for a maximum load of 150 kg.

6.8.2. Operation of the Patient Bed Type "I"

The patient bed type "I" is in operation after switching ON the Excimer laser. The patient bed is only intended for short periods of operation. Exceeding the permissible operational time limit, the thermal protection switch interrupts the electronic function. After a cooling-off period (approx. 30-50 Min.), the bed is again fully operational.

To change the position of the bed in the intended X and/or Y axis, push the joystick in the desired direction. To move the patient bed up or down (Z axis) turn the head of the joystick in accordance with the arrows.

Moreover, the joystick allows exact regulation of adjustment speed and precise patient positioning.

As long as the foot switch is pressed during a treatment, it is not possible to move the bed in any direction. This protects against unintended movement of the patient bed during treatment.

Figure 20: Patient bed Type "I" with joystick

The patient bed offers two special functions which allow fully automatic operation to the best entry and exit positions and a freely selectable position (by pressing the buttons ***'Store'*** and ***'Memo'***).

The freely selectable treatment position of the patient bed can be stored any time by pressing the ***'Store'*** button. By pressing the ***'Memo'*** button, the last stored position of the patient bed can be recalled and the bed moves automatically in this position.

IMPORTANT NOTE

The automatic functions can be interrupted any time by operating the joystick.

At the beginning and after finishing of the treatment, the bed can be brought automatically to the most comfortable IN/OUT position for the patient by pressing the ***"IN/OUT"*** button next to the joystick.

The three motors moving the bed in the X, Y and Z axis are constructed for an operating time of 1 minute, after this time a break of 9 minutes is necessary. Furthermore, the motors are constructed for max. 5 switching cycles (forward, backward, right, left, up, down) per minute.

6.9. Patient Bed Control Type "II"

6.9.1. General

For the patient bed Type "II", please see the following description in chapter: "Operation of the Patient Bed Type "II".

The patient bed is designed for a maximum load of 150 kg.

6.9.2. Operation of the Patient Bed Type "II"

The ESIRIS patient bed type "II" is in operation after switching ON the Excimer laser.

A micro-processor controls analogy (proportionally) joystick movements of the OP-table.

The patient bed facilitates the proper positioning of the patient underneath the microscope and has a smooth and soft start in all 3 directions/axes (x,y,z). All of these controlled joystick movements (up/down, forth/back, left/right) and the auto-down function are working smoothly for positioning in any desired direction.

Standard operation of the patient bed allows adjustment of height, lateral and longitudinal axes by means of a joystick. The joystick allows exact regulation of adjustment speed and precise patient positioning.

To change the bed position in the desired direction (up/down, forth/back, and left/right) the joystick has to be moved according to the arrows on the operation console.

The joystick movements have a smooth and soft start for all 3 axes (x,y,z).

Moreover, the joystick allows exact regulation of adjustment speed and precise patient positioning.

Figure 21: Patient bed type "II" – operation console

As long as the foot switch is pressed during a treatment, it is not possible to move the bed in any direction. This protects against unintended movement of the patient bed during treatment.

At the start and after completion of the treatment, the bed can be brought automatically to the most comfortable entry and exit position for the patient.

This function will be released by pressing the button next to the joystick.

The IN/OUT function is activated by pressing the button (7), which moves the bed to the entry/exit position.

IMPORTANT NOTE

A slight movement of the joystick is enough to interrupt the AUTO function.

If required, the joystick assembly can be remounted to the other side of the bed by a service technician on location.

See Figure 22: Patient bed type “II” - joystick operation

1 - Back

2 - Forth

3 - Left

4 - Right

5 - Up

6 - Down

7 – IN-OUT

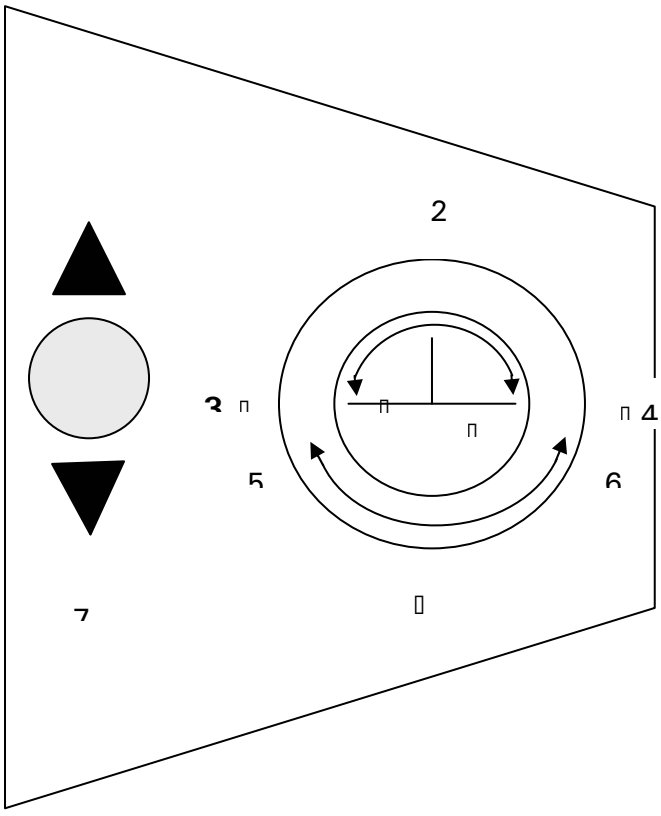


Figure 22: Patient bed type “II” - joystick operation

6.10. Software Managed Operation of the Excimer Laser

To select the desired function in a menu use the keyboard arrow keys ↑ and ↓, the TAB button or the mouse pointer to the desired menu. The active button will be displayed with a black border. Then simply press **ENTER** or click with the left trackball button.

6.10.1. User 'Login'

After starting the system, the Login menu appears (see Figure 23: User login). Enter your user name and your personal password.

6.10.1.1. Password Input

This password is managed by the administrator (for example the medical director) and stored at **'Password administration'**.

The first issuance of the password will be accomplished by specialists / technicians of the SCHWIND eye-tech-solutions during the hand over of the SCHWIND ESIRIS.

The following figure shows the user **Login menu**:

Figure 23: User login

In the ESIRIS **Login menu** you can select language and active nomogram.

6.10.1.2. Function 'Change Language'

The language may also be selected within the Login menu. To change language selection, press the button Language selection and the list of choices appears. The selection will be stored as your standard language and it can be changed any time.

This is shown in the following figure:

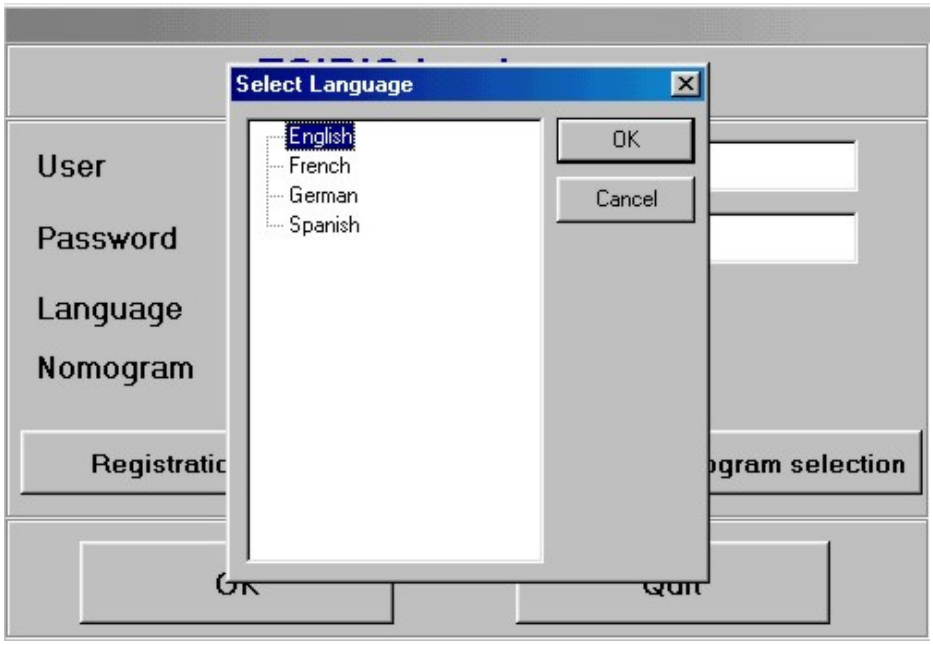


Figure 24: User login with language selection

To confirm the selected language press the button OK and the Main Menu appears.

6.10.1.3. Function 'Registration'

The laser will be activated for treatments using the function **'Registration'**.

The first registration in the ESIRIS laser will be carried out by a service technician or product specialist from SCHWIND eye-tech-solutions.

There are two procedures to activate the laser for treatments:

- Activating the system for a specific period of time
- Activating the system for a specific number of treatments

The system can be activated for each user individually or for all users together.

You'll receive the activation code from SCHWIND eye-tech-solutions. This code must be entered in the mask shown below:

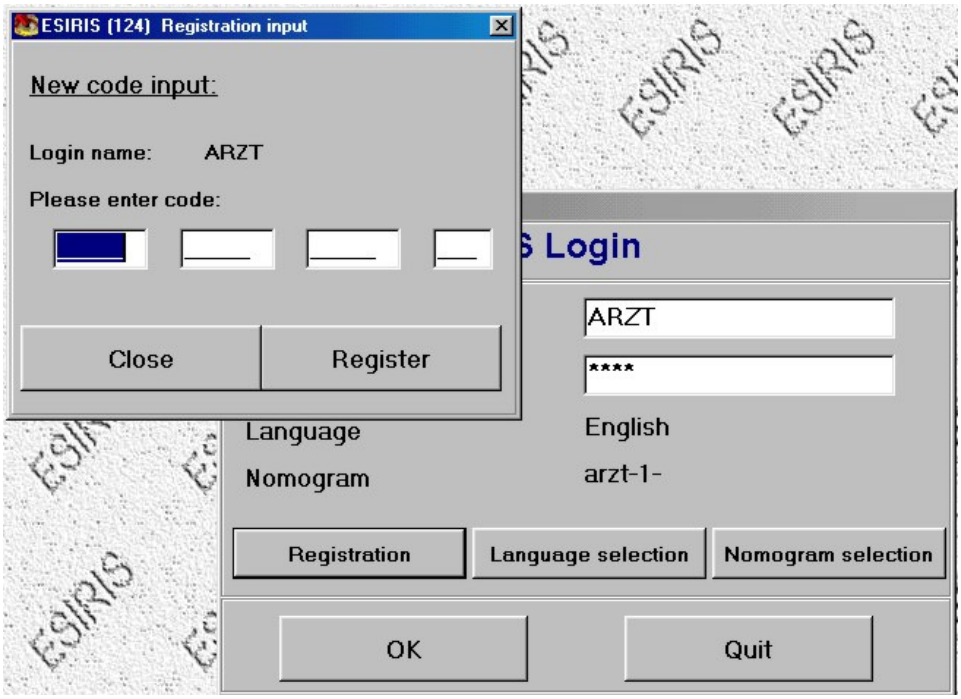


Figure 25: Registration

In this menu the name of the user is shown. Enter the activation code and press the button Registration.

In the Help Menu under **'Registration'** you'll find the information regarding remaining period of treatment time or how many treatments are still available.

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It is important to keep in reserve one or two registration codes for possible emergency cases, for example '**Recovery'** function.

6.10.1.4. Function 'Choose Nomogram'

The nomogram function automatically considers parameters as age, diameter of optical zone as well as the cylinder value for the spherical ablation for all standard treatments.

A detailed description of the nomogram function can be found in the OP-Manual.

After pressing the button **Nomogram selection** a submenu appears, where you can choose from different applied nomograms (see Figure 26: Nomogram menu). The

desired nomogram can be chosen from the list **'Available nomograms'** using the cursor and at the same time it will be displayed in the information window.

For one Excimer laser system only a maximum of 29 various nomograms can be created. A miniumum of one nomogram per user will be created.

This window also displays optional user information, creation date and time and creator of the nomogram.

With the **Print** button you can print out the active nomogram with all its factors and parameters.

With the **Export** button you can export an active nomogram to any storage device.

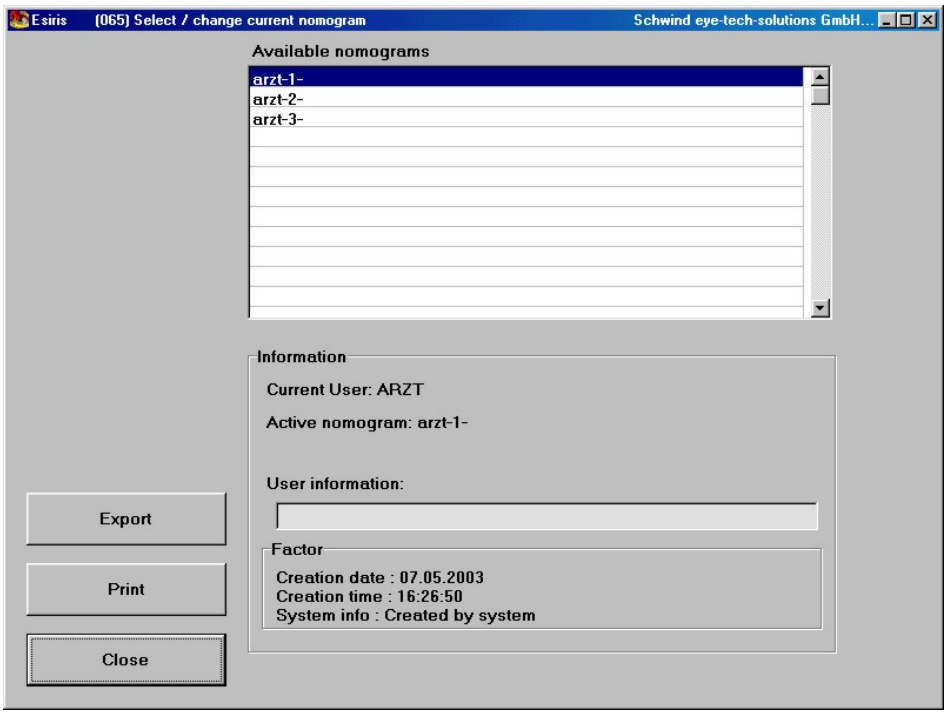


Figure 26: Nomogram menu

IMPORTANT NOTE

It is not necessary to choose a nomogram every time the program is started. The system will automatically use the most recently activated nomogram.

To exit this menu, press the **Close** Button and the Main Menu will appear.

6.10.2. Main Menu

After switching on the system, it performs a self check and runs through a warm up phase, which can take a few minutes.

After login, the Main Menu appears.The Main Menu contains the options to choose various treatments and operating procedures for laser operation (see Figure 27: Main menu). After choosing the buttons **User Administration, HS-Fluence Test, Gas change,** or **PMMA Test** etc. you can select the appropriate sub-menus.

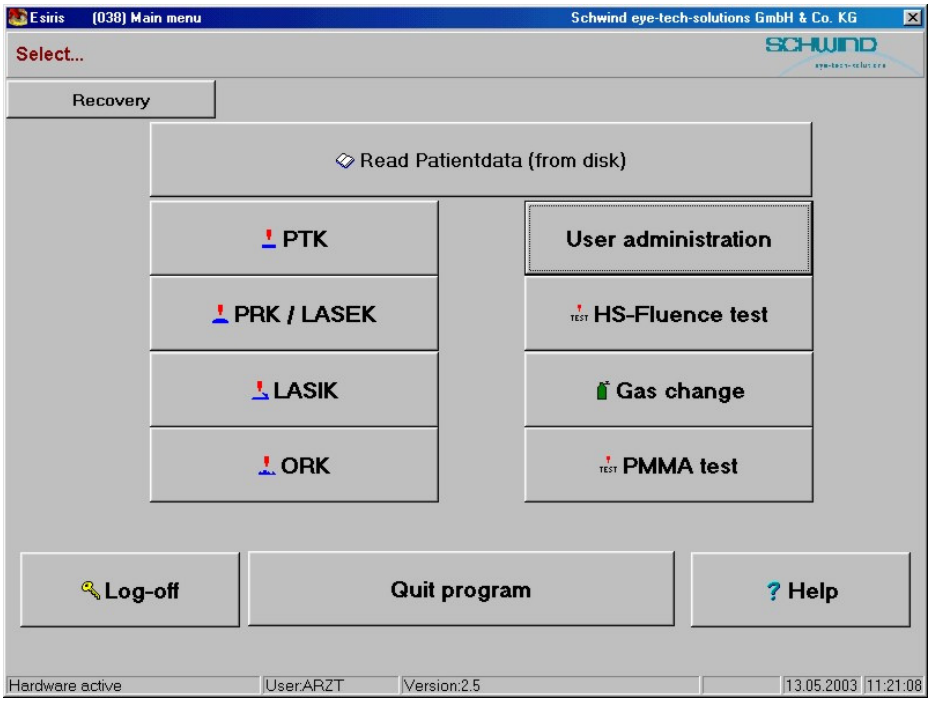


Figure 27: Main menu

To select the desired function use the keyboard arrow keys ↑ and ↓, the **TAB** button or the mouse pointer to the desired menu. The active button will be displayed with a black border. Then simply press **ENTER** or click with the left trackball button.

IMPORTANT NOTES

All entries in menus, i.e. refraction, axis, etc. must be confirmed with the ENTER-key. For your own certainty all entries should be checked that they have been correctly taken over by the system.

An open menu or a started function can be left by selecting the menu option **'Back to main menu'** (= Button) and pressing **ENTER**.

Before each treatment a further short self check will be performed.

Troubleshooting

If after the self test of the system an error message appears:

- Shut down the system, switch off, again switch on, start the program again.

If the error arises again:

- Inform the service department of SCHWIND eye-tech-solutions and describe the error message.

7. SERVICE PROCEDURES

7.1. General

Determined service procedures are essential for operation of the Excimer laser. They can be chosen in the Main Menu and they contain the following single functions:

- **User Administration (for the Medical Directory only)**

  To create and delete of users (refer to chapter 7.2)
- **Fluence Measurement and Drift Test**

  To calibrate the system (refer to chapter 7.3)
- **Gas Exchange - Excimer Laser**

  To change the gas fill in Excimer laser (see 7.4)
- **Gas Exchange - Excimer Laser**

  For regular functions and adjustment checks (refer to chapter 7.5)
- **Help Menu** (refer to chapter 7.6)

IMPORTANT NOTE

Usually at the beginning of an operation day only the functions HS-Fluence test and gas changes are necessary.

7.2. User Administration (for the Medical Directory only)

The button **User administration** is active when the system administrator has logged on to the system with his password.

In this menu you can manage the user names and passwords. The function allows assigning each doctor his own password in the treatment file in order to see which doctor performed a treatment.

To enter this menu, a special password is required that should only be known by the medical director or administrator.

After the entry of the correct password, the following menu appears:

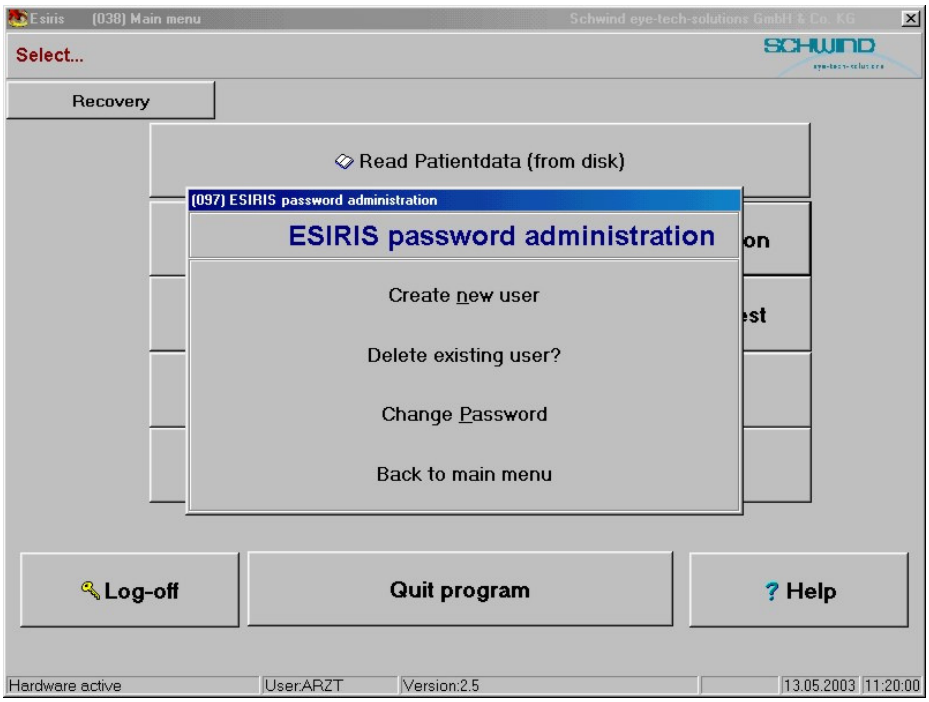


Figure 28: Menu 'Password administration'

The menu contains the following functions:

'Create new user'	Allows the creation of a new user with password.
'Delete existing user'	Shows the list of all users. There is the possibility to delete a user.
'Change Password'	Existing passwords can be changed for the individual user.
'Back to main menu'	The user can return to the system main menu.

7.3. Fluence Measurement and Drift Test

7.3.1. General

The fluence measurement is used for calibration of the system. This is carried out by firing the laser onto a special foil. The system determines the number of pulses required to completely perforate the foil. The ablation rate is calculated according to predetermined parameters. The fluence measurement is followed by the drift measurement, which serves to monitor the laser beam control and increases the accuracy of the system.

7.3.2. Execution of a Fluence Test

When should a Fluence Test be carried out?

- At the beginning of each treatment day.
- Every 2 hours – or
- After 500.000 laser pulses
  After 24 hrs or 500.000 laser pulses only 5 more treatments are allowed and the system does not allow further treatment.

For the execution of Fluence Test, a special test device (Fluence Detector) is supplied with the system (see Figure 29: Fluence detector with HS-foil – Holder patient bed type "II" and Figure 30: Fluence detector with HS-foil – Holder patient bed type "I").

Figure 29: Fluence detector with HS-foil – Holder patient bed type "II"

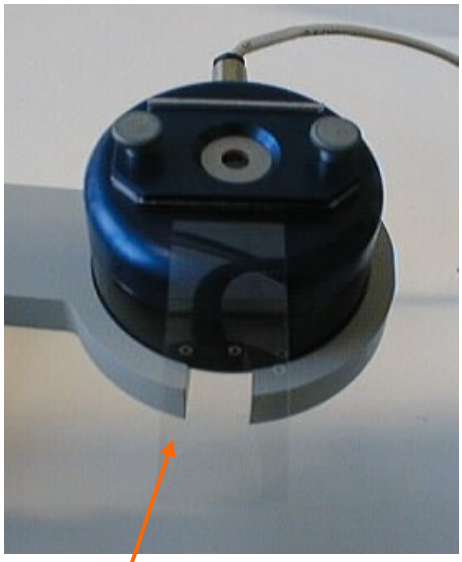


Figure 30: Fluence detector with HS-foil – Holder patient bed type "I"

It consists of a blue metal housing equipped with a fixation device for securing of the HS-foil. Inside this holder is a titan dioxide detector which is covered with a sapphire glass and fluoresces when contacted by UV-radiation appears. This fluorescent light is detected with sensors and evaluated by the control unit.

As long as the foil isn't perforated, no laser beam can reach the detector through the glass plate. This means no signal will be transferred to the computer. Upon starting of the perforation, ablation of the entire diameter of the measured quantity of UV light increases continuously until reaching a maximum point. Then the test will be evaluated and finished automatically.

IMPORTANT NOTE

To minimize any influences on the measurement the following must be observed:

- Place the HS-foil always under the second, silver-coloured plate of the fluence detector.
- Clean the glass window of the fluence detector from ablation remains every time before a new fluence test starts.
- Carry out the fluence test without interruption, i.e. press the foot switch continuously until the fluence test is completed.
- During the fluence test, the patient bed is blocked and should not be touched.
- Avoid any sun light in the room during the treatment.
- The HS-foil is ultraviolet-light sensitive. Store the HS-foil light-tight to avoid quality and conditional changes of the foil, which could vary the ablation rate during the fluence test.

To clean the window of fluence detector – do not use alcohol or liquids containing ammonia! Such agents could prevent the successfully execution of a fluence test, or result in over-/under corrections during treatment.

To perform the Fluence Test the following steps must be performed:

(1) Place the HS-foil under the second, silver-coloured plate of the fluence detector.

(2) Focus and centre the ablation height on the HS-foil using both position lasers.

(3) Reduce the light in the room and switch off the illumination of the treatment area.

(4) Push button **HS-Fluence Test** in the Main Menu and follow the messages on the monitor.

(5) Check on the monitor that the adjusted position of the sensor is located in the centre of the camera picture (live photo).

(6) Wait until message **"Press Foot Switch"** appears. The foot switch must be pressed down now and remain pressed until the system ends the test (see Figure 31: Start of fluence). The fluence test starts and ends automatically.

(7) After completion of the Fluence Test a message appears that a Drift Test will be performed.

(8) To avoid damages to the foil, it has to be carefully packed after the use.

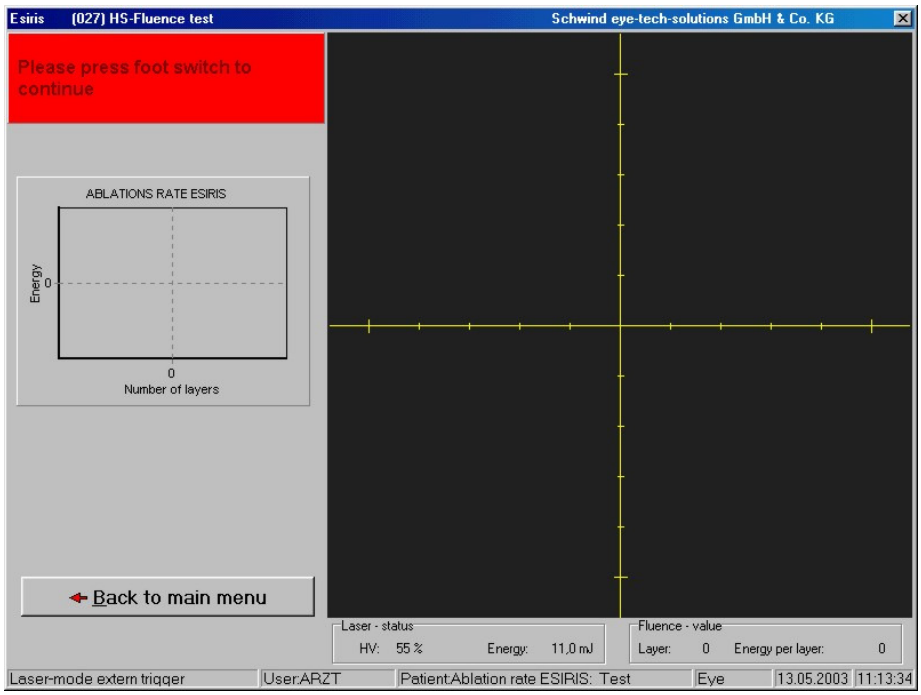


Figure 31: Start of fluence test

7.3.3. Execution of a Drift Test

The Drift Offset Test is used for checking the laser beam guidance and the scanner unit. It will be carried out after each Fluence Test.

IMPORTANT NOTE

To minimize any influences on the measurement the following must be observed:

- After start of the Drift-Offset-Test, the patient bed will be blocked and should not be touched. It is not possible to correct the position.
- The test has to be carried out without interruption, i.e. press the foot switch continuously until the drift test is completed.

Figure 32: Fluence detector with photo paper

To perform the Drift Test the following steps must be performed:

(1) Place the photo paper between the blue and silver-coloured plate of the fluence detector and fix it with the blue plate (see Figure 32: Fluence detector with photo paper).

(2) Justify the photo paper. Only the black photo paper should be seen on the live-photo on the screen. Afterwards adjust the ablation height by using the positioning lasers.

(3) Confirm the message **"Please put the photo paper in the focus point and press OK"**, see Figure 33: Start of drift test. The Drift-Offset-Test will start.

(4) A message will ask the user to press the foot switch. After pressing the foot switch, the measurement procedure will be performed automatically.

(5) The result will be shown on the screen. Confirm with OK

(6) In case the drift measurement was not successfully executed, it is possible to repeat it up to three times. In this case you have to start the procedure from point (1) 'Inserting the photo paper' step by step to repeat.

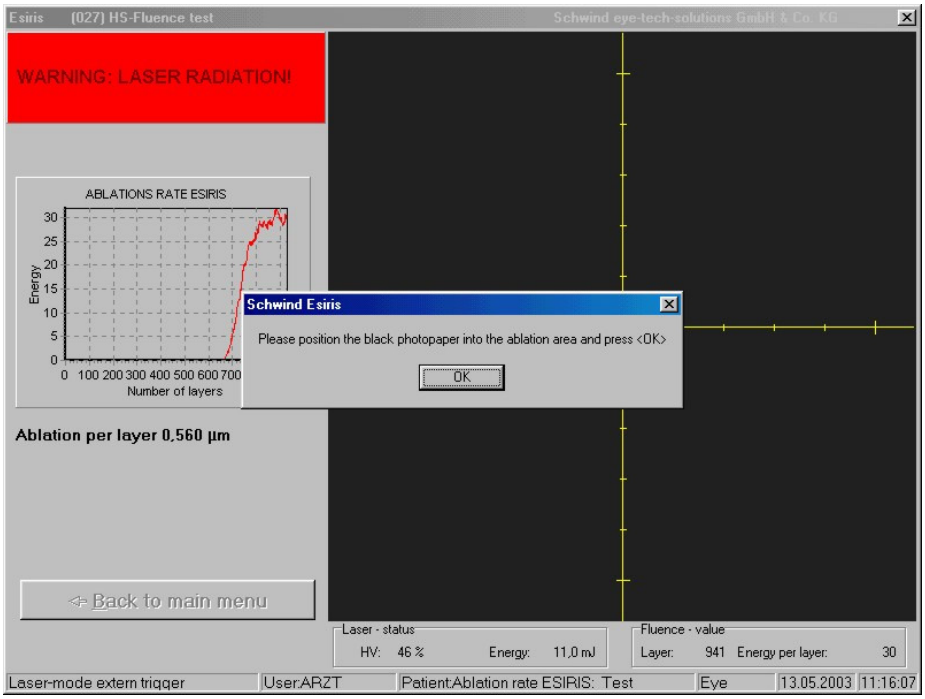


Figure 33: Start of drift test

7.3.4. Measurements Completed

After the fluence and drift measurements have been performed successfully, the message **"Fluence Test OK"** appears on the screen, see Figure 35: Fluence test successfully completed.

The procedure Fluence Measurement is finished.

The measured value for the Fluence Test will be displayed. The value shows the calculated ablation per pulse at the human cornea.

You can print out the fluence test results by pressing the printer symbol above the fluence graphic.

SCHWIND eye-tech-solutions

Fluence test

Laser serial number:	2		
Software version:	2.5		
User:	ARZT	Date:	13.05.2003
Clinic / City:	NoClinic / NoCity	Time:	11:17:59

Fluence test results

Ablation rate	0,560 µm/L.	Scanner	180µm 252°
Lower ablation rate limit	0,495 µm/L.	Preset laser energy	11,00 mJ
Upper ablation rate limit	0,605 µm/L.	Laser repetition rate	200 Hz

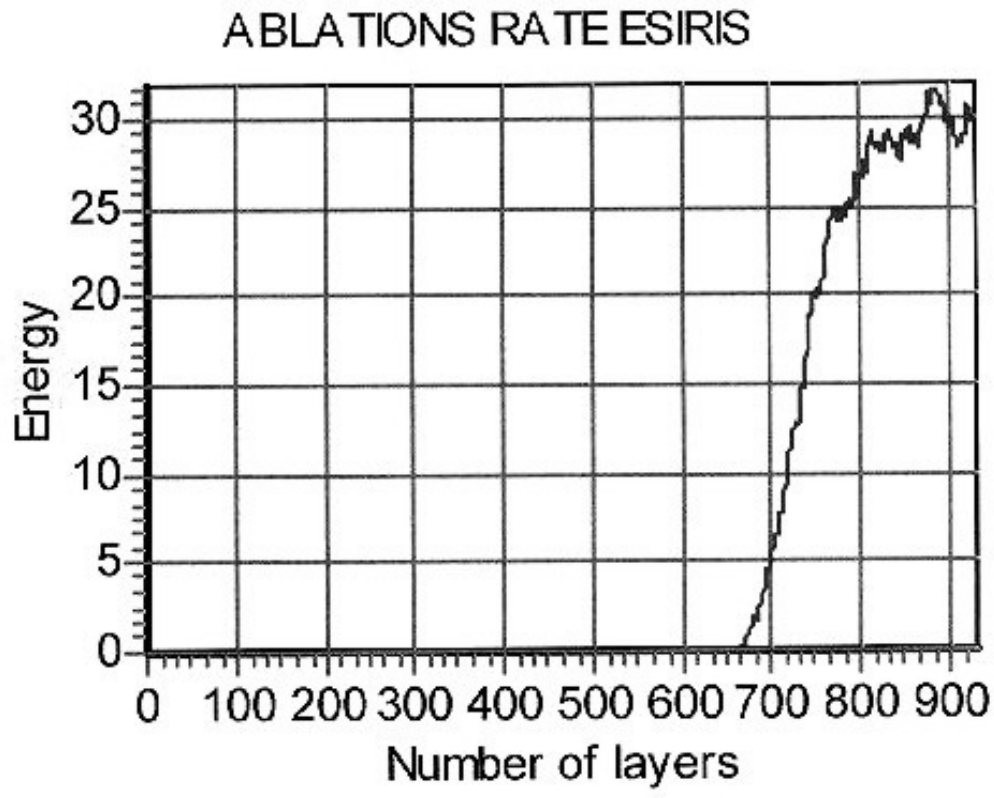


Figure 34: Fluence test results

The actual result will be stored by the software and will be used to calculate the needed number of pulses for the following treatments.

If the test result is negative, treatments cannot be performed with the system.

Press **ESC** to go back to the main menu.

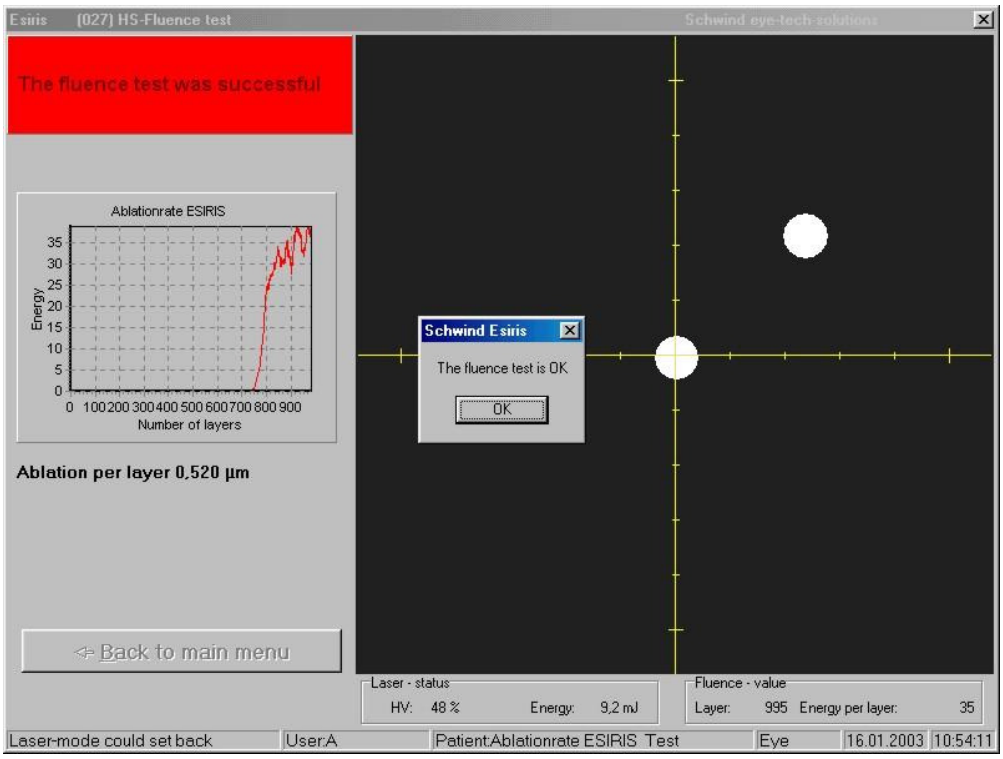


Figure 35: Fluence test successfully completed

IMPORTANT NOTE

During the fluence test the perforation has to be observed via the microscope or the video screen (monitor). If the optical system is aligned correctly, the perforation of the foil starts in the centre of the ablation spot. It has to proceed symmetrically to the outer edge.

Small deviations of the perforation are normal and acceptable. Only a trained engineer can do a proper evaluation.

7.3.5. Troubleshooting

What to do if:

The first fluence test has not been performed successfully

- Execute a gas change
- Clean the fluence detector
- Reduce environmental light
- Check, if the HS-foil is correctly placed

The fluence test is not successful after a gas change

- Perform another gas change (especially if the laser was not used more than one week, it is usually necessary to do 2-3 gas changes).

The fluence test is not successful despite repeated gas changes

- Please contact the service department of SCHWIND eye-tech-solutions.

The first drift measurement is not successful

- Check again on the screen that before beginning the drift measurement the screen is completely black.
- Again check the correct position of the photo paper with the two position lasers. (The spots of both position lasers have to meet in one point).
- Make sure that during the test no one touches the laser.

The third measurement is still not successful

- Please contact the service department of SCHWIND eye-tech-solutions.

What happens if:

The fluence test or the drift measurement is not successful and/or the time since the last fluence test becomes too long?

- In this case, for safety reasons, the system does not permit any treatments.

7.4. Gas Exchange - Excimer Laser

7.4.1. General

The laser source is a gas filled tube that emits the Excimer beam.

IMPORTANT NOTE

The operating time of the gas is limited by the number of released pulses and by the time the gas is inside the laser tube.

When is a gas exchange necessary?

- Fluence test cannot be started at all based on too low energy.
- Laser has not been used for over one week.
- When the software requires the gas change.

7.4.2. Execution of a Gas Change

To start the procedure, select the corresponding menu point **'Gas change'** in main menu and press **ENTER/Mouse** button. A sub menu appears as shown in Figure 36: Start of a gas change.

You will be asked if a gas change should be performed. To start it, select the button **OK.** After that the gas change starts automatically.

After the laser tube is filled up to 4400 mbar with fresh premix gas (older lasers partly to 3400 mbar) the procedure is finished and the following window appears (see Figure 37: Gas change OK).

The gas exchange is now successfully completed.

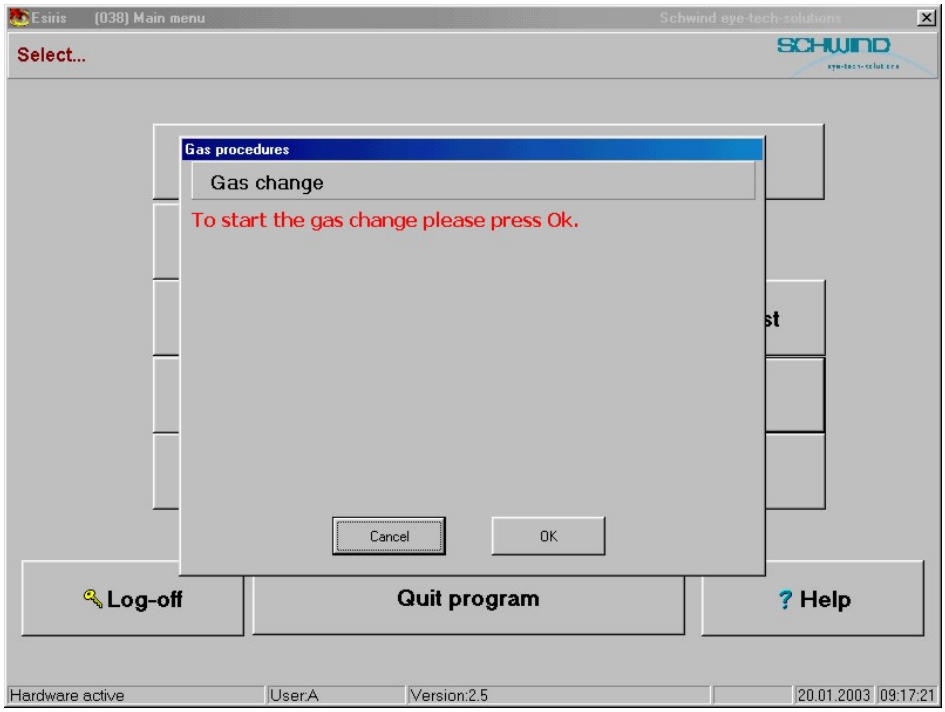


Figure 36: Start of a gas change

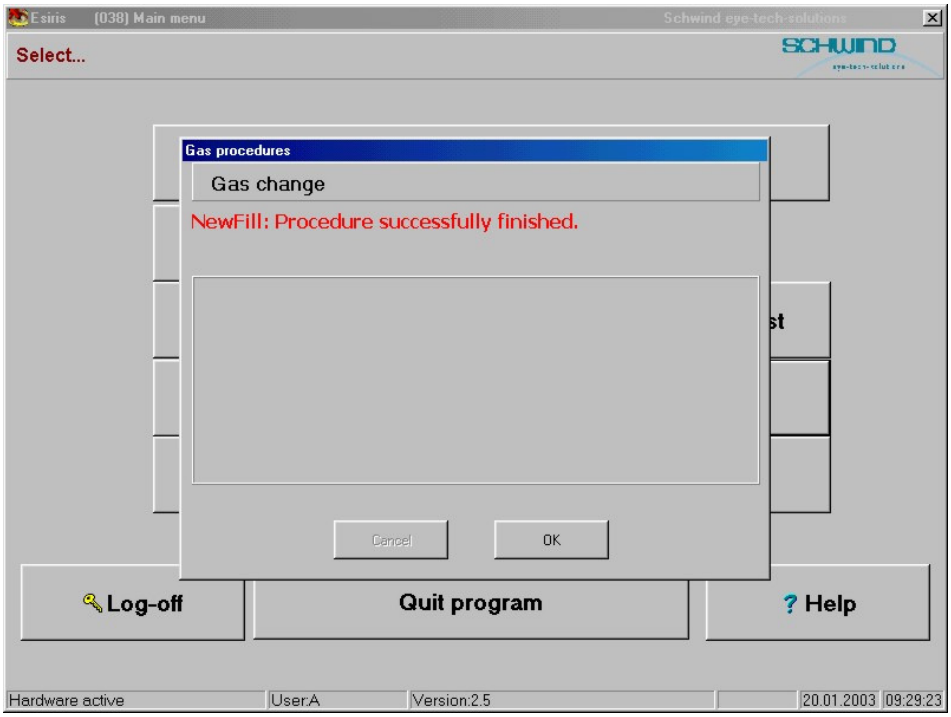


Figure 37: Gas change OK

7.5. PMMA Test

7.5.1. General

A PMMA test is an ablation test which is regularly performed as an additional check of the correct system operation and system adjustment. For this purposes a special PMMA (Polymethylmetacrylat) plastic die will be used. The PMMA test serves as quality control.

IMPORTANT NOTE

The PMMA test must be carried out every 1 million laser pulses.

The PMMA plates are included in scope of supply of ESIRIS and may be further obtained from SCHWIND eye-tech-solutions or an authorised representative.

If a PMMA test is required, a message appears on the screen after logging in to the system notifying you that a PMMA test must be performed.

After activating the button **PMMA-Test** in the main menu, the PMMA test will start. The following menu will appear on the monitor:

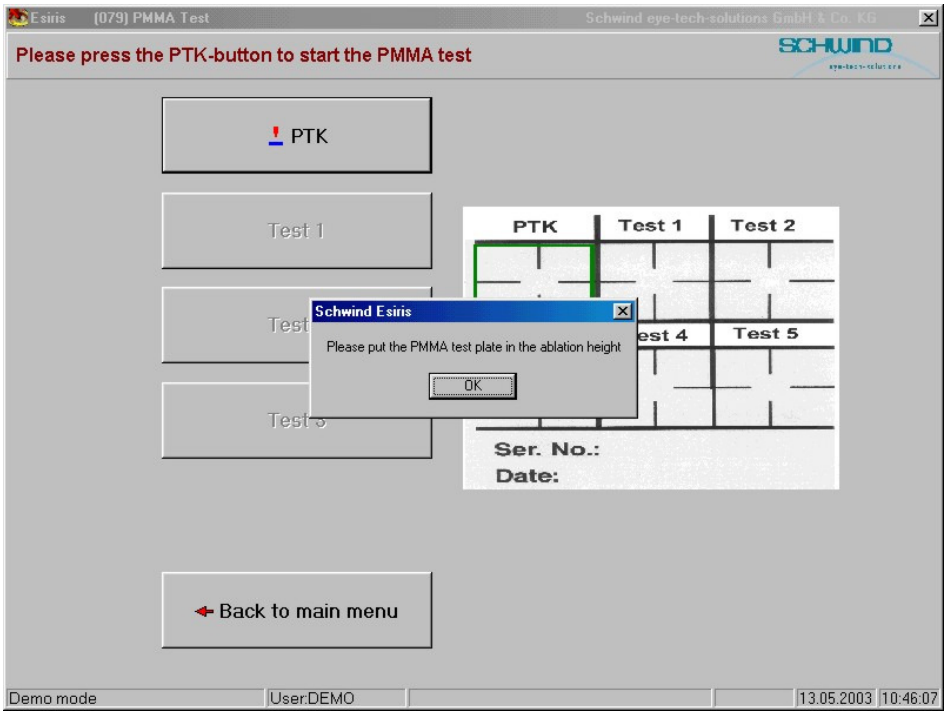


Figure 38: PMMA test

7.5.2. Execution of a PMMA Test

IMPORTANT NOTE

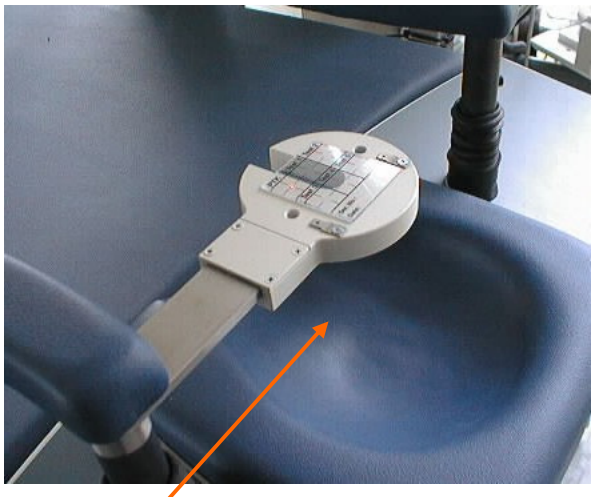
Please pay attention!

- In order to ensure the best possible test result, the test procedure of the ablation must be performed without interruption and the test the bed should not be touched
- It is important to choose the **Continue** button until all tests are completed and the notification on the right side of the screen (virtual PMMA plate) shows 5 checked fields.

The execution of this test is very easy and will be performed as described below. Use one of the PMMA dies which are included in the delivery of the laser.

(1) Remove the protective foil from the PMMA plate and position the plate on the top of the fluence detector holder (see Figure 39: PMMA plate on the holder of patient bed type 'II" and Figure 40: PMMA plate on the holder of patient bed type 'I"

(2) With the type “II” patient bed you first remove the head rest and then place the cylindrical holder in the now free area. The holder is included in the scope of supply of the ESIRIS.



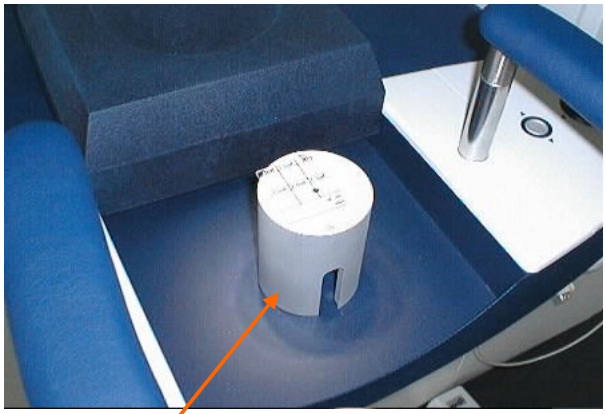


Figure 39: PMMA plate on the holder of patient bed type 'II"

Figure 40: PMMA plate on the holder of patient bed type 'I"

(3) Position a very thin and plane piece of paper on the top surface of the plate (The paper supports to match the two laser spots of the positioning laser at the top surface of the plate). The paper has to lay flat on surface of the paper and must have direct contact with the PMMA plate.

(4) Match the laser spots using the joystick of the patient bed (Height control of patient bed)

(5) When two laser dots are on top of each other remove the piece of paper and place the first ablation square **PTK** in the treatment area.

(6) Choose the highlighted test procedure (the active field will be highlighted with black letters) and centre the respective ablation field (i.e. For PTK test the PTK ablation field) of the PMMA plate with the aid of the live picture on the computer screen.

(7) The ESIRIS laser will now perform a warm-up phase operation, after which time you will be instructed to press the foot switch, thus beginning the test procedure.

(8) After completion of the PMMA test (it takes place automatically) press the button **Continue** and you will return to the PMMA menu. Now the next test sequence will be activated and proceed starting from point (6) of this description.

(9) After completion of all tests, press the button **Back to main menu**, which will be followed by a message **"PMMA test successfully completed"**.

The successfully completed tests will be saved in the software and this will reset the notification message requesting you to perform a new test according to laser pulse limits.

(10) Mark down with a waterproof pen the serial number of your ESIRIS and the date of the PMMA test on the completed PMMA plate and send the plate to SCHWIND eye-tech-solutions or responsible representative.

The ablations will be checked with a precise optical profilometer and compared to a rated value. The customer will be informed of the result immediately.

7.6. Help Menu

In the help menu the operating instructions and the OP manual are posted again for reference. Here you will also find the address of SCHWIND eye-tech-solutions, the software version, the serial number of your device, the current registration status and thereby the number of treatments remaining.

With the **'Service'** function you can export the Log file, treatment data and the settlement data.

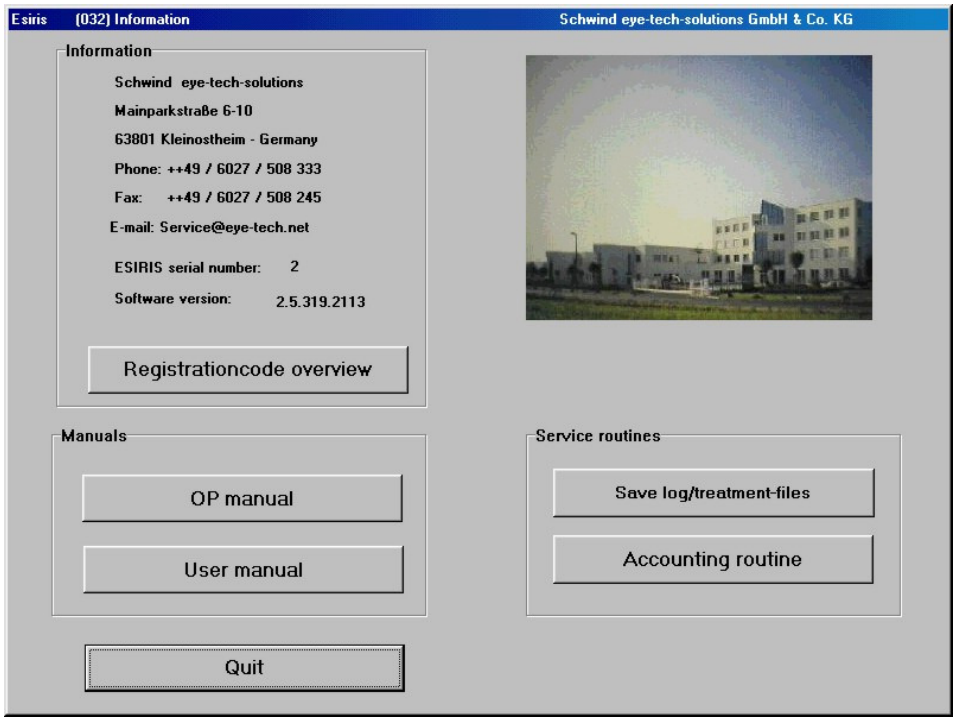


Figure 41: Help menu

7.6.1. Export of Log File and Treatment Data

In case of system failure caused by a technical defect, it may be necessary to copy the log file and treatment data onto a storage medium and forward the same to SCHWIND eye-tech-solutions. Usually this is done in consultation with the Service Department of SCHWIND eye-tech-solutions or your distributor.

- For this, a submenu is activated with the button **Save log/treatment files.** First you have to select the source file in this submenu. Just click on **Source** and then on **Logfile** or **Logfiles and treatment files**.
- In case you wish to copy the treatment files, a window opens where you can indicate the time period in which the data should be copied.

- The next step is to select the target drive with the button **Destination**. You may use A: floppy disk drive, D: CD-ROM writer (not with older ESIRIS systems) and E: USB memory stick.
- Click on **Copy** after selecting the storage medium. The file size and available memory are displayed in this menu again. The selected data is stored by activating the button **Copy**. You may send this to the Service Department of SCHWIND eye-tech-solutions.

7.7. Log-OFF – User Change

This function allows protection of the ESIRIS against unauthorized use if, for instance, the surgeon leaves the room. This function is also used to change the user name if another surgeon will perform a treatment. This ensures that the entries/records in the treatment file are correct and the possibility of the data reconstruction is guaranteed.

8. TREATMENT SELECTION

8.1. General

After the fluence test has been carried out successfully, the appropriate treatment can be chosen and the patient data can be entered.

On the left side of the Main Menu you can select the relevant **PTK, PRK/LASEK, LASIK ORK** treatment.

After selection of the required treatment, the appropriate sub-menu will appear.

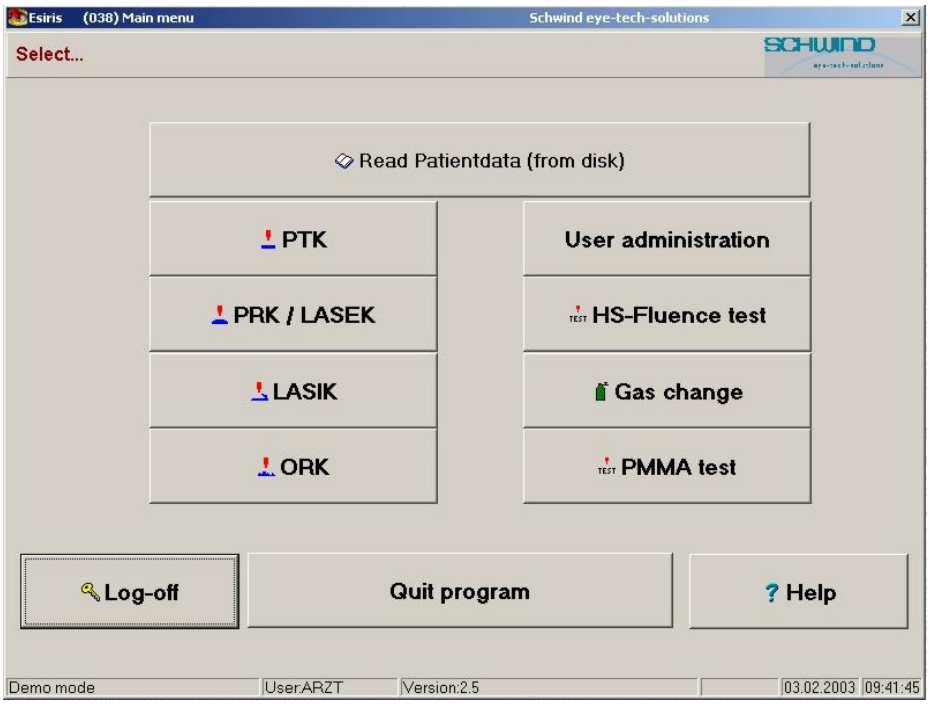


Figure 42: Main menu ESIRIS

Using the function **‚Read Patient data (from disk)'** you can directly read the treatment data.

8.2. PTK Treatment

8.2.1. General

The PTK treatment enables a consistent ablation with a defined ablation depth as well as defined diameter of ablation on a certain area of the human eye for various treatments.

8.2.2. Input of Patient and Treatment Data

Definition: PTK = Phototherapeutic Keratectomy

After selection of the function **PTK** in the Main Menu, the **PTK menu** for input of patient data appears (see Figure 43: PTK input menu).

In this menu will be calculated the quantity of treatment layers based on the fluence value for the treatment setting parameters.

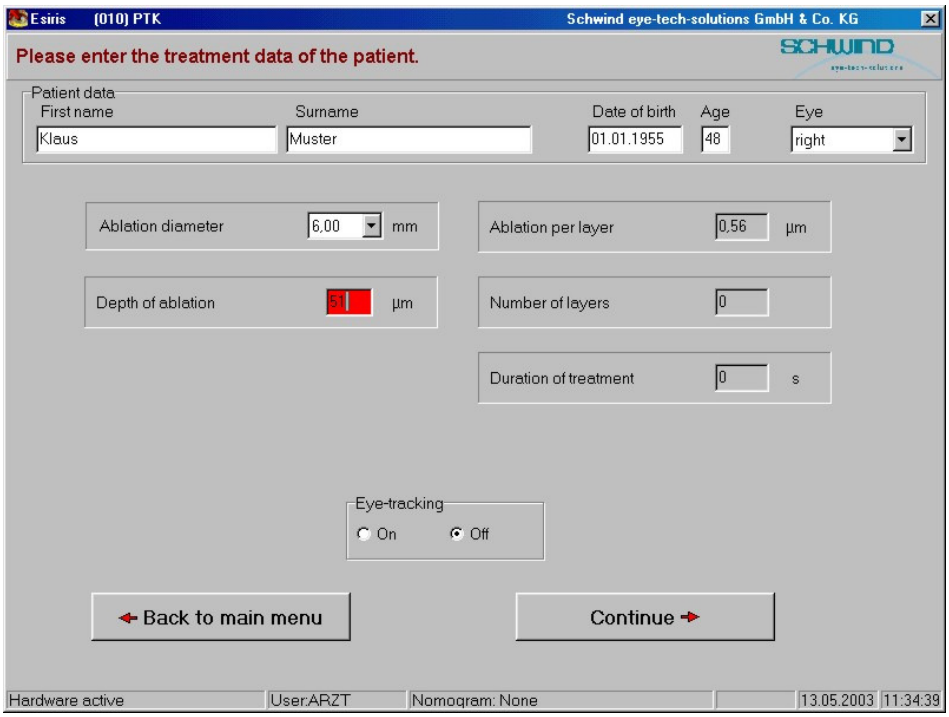


Figure 43: PTK input menu

Inputs required for treatment:

'First Name'	Enter the patient's first name.
'Surname'	Enter the patient's surname.
Date of birth'	Enter the patient's date of birth (DD.MM.YYYY).
'Age'	After input of the patient's date of birth, the age of the patient appears automatically. To start a treatment, you have to enter either the date of birth or the age of the patient.
'Eye'	Define the eye to be treated.
'Ablation diameter'	Enter the diameter of intended ablation zone in mm.
'Depth of ablation'	The maximum depth for the treatment should be defined.

The 3 information lines on the right side of the input menu (see below) indicates the corresponding values to the inputs you entered.

Values calculated from the system:

'Ablation per layer'	It indicates the result of last fluence test.
'Number of layers'	The calculated number of layers will be displayed. It consists of the fluence test value and the ablation depth.
'Duration of treatment'	It indicates the time of the treatment in seconds. This is determined by the system and depends on the ablation per layer and the treatment parameters.

If necessary, the **eye tracking** can also be alternatively switched on and off in the PTK input menu.

To get to the main treatment menu, press the button **Continue**.

To get back to the Main Menu, press the button **Back to main menu**.

8.2.3. Execution of a PTK Treatment

After selection of the button **Continue** the treatment screen will appear (see Figure 44: PTK treatment menu).

The laser performs a self test now, which can take some seconds.

Explanation of treatment screen

'Depth of ablation' It indicates the already ablated depth (left number). The right number shows the intended ablation depth.

'Duration of treatment' It indicates the duration of the treatment in seconds. It is determined by the system and depends on the ablation per layer and the treatment parameters, and especially on the depth of ablation. The left number shows the already reached treatment time, the right number shows the maximum treatment time.

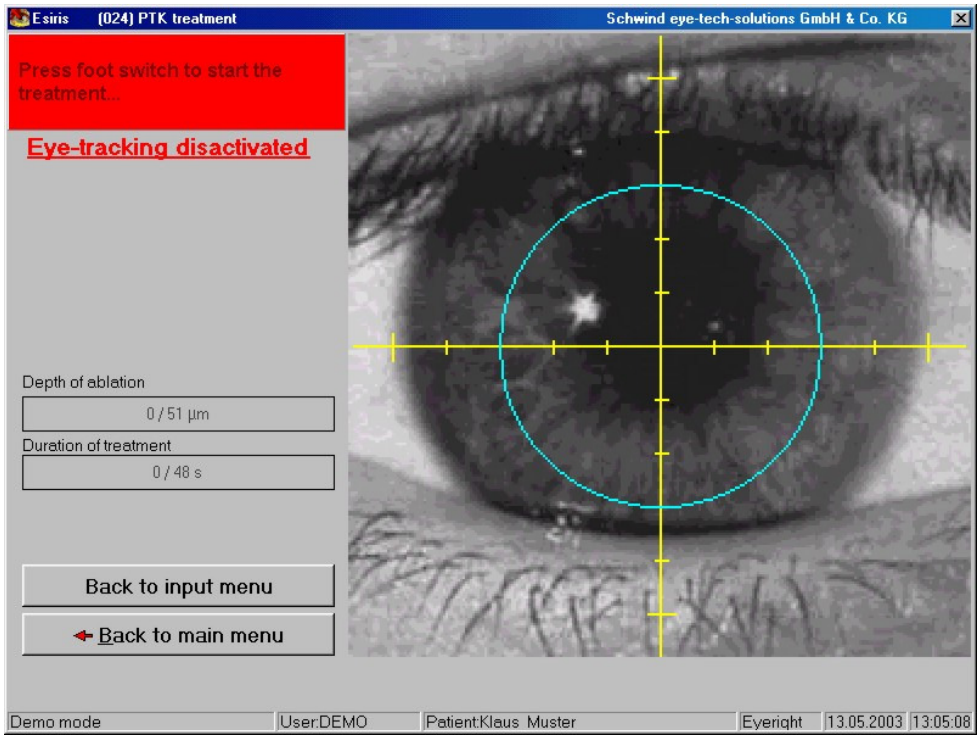


Figure 44: PTK treatment menu

On the right half of the monitor the live picture of the eye is displayed. The centre of the crosshair marks the centre of ablation with deactivated eye tracker.

(1) It is important to bring the eye into the desired treatment position. For this purpose the patient must be brought into position by operating the patient bed until the crosshair of the live photo meets the centre of the desired ablation zone.

(2) Focus height is achieved by merging the two position laser beams.

(3) After the successful completion of the self test, an instruction **"Press foot switch to start the treatment"** appears.

(4) To start the treatment procedure or to release the laser pulses, press the foot switch completely down (2 steps).

(5) When the foot switch pedal (completely or just one step) is released, the treatment is temporarily interrupted and can be continued by pressing the pedal down again at the interrupted position.

(6) To continue a treatment of a second eye (with new data input), press the button **Back to input menu**

(7) After completion of the treatment, press the button. **Back to main menu.**

(8) After pressing these buttons, you will be asked if the treatment data should be printed.

8.3. PRK /LASEK Treatments

Definition: PRK = Photorefractive Keratectomy

8.3.1. General

PRK treatment is an operation method which allows the excise correction of the various kinds of ameropia of the human eye.

8.3.2. Selection of Treatment

After selection of the function **PRK/LASEK** in Main Menu, a PRK submenu will appear (see Figure 45: Treatment selection PRK).

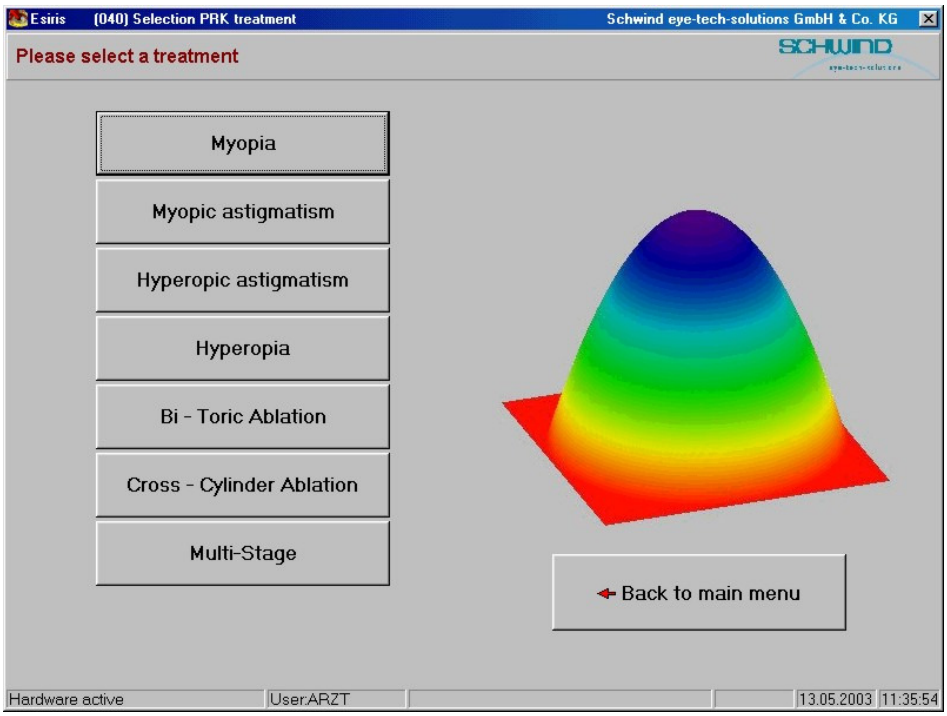


Figure 45: Treatment selection PRK

In this menu the desired type of treatment can be chosen to enter the treatment values.

8.3.3. Sample of PRK Treatment – Myopic Astigmatism

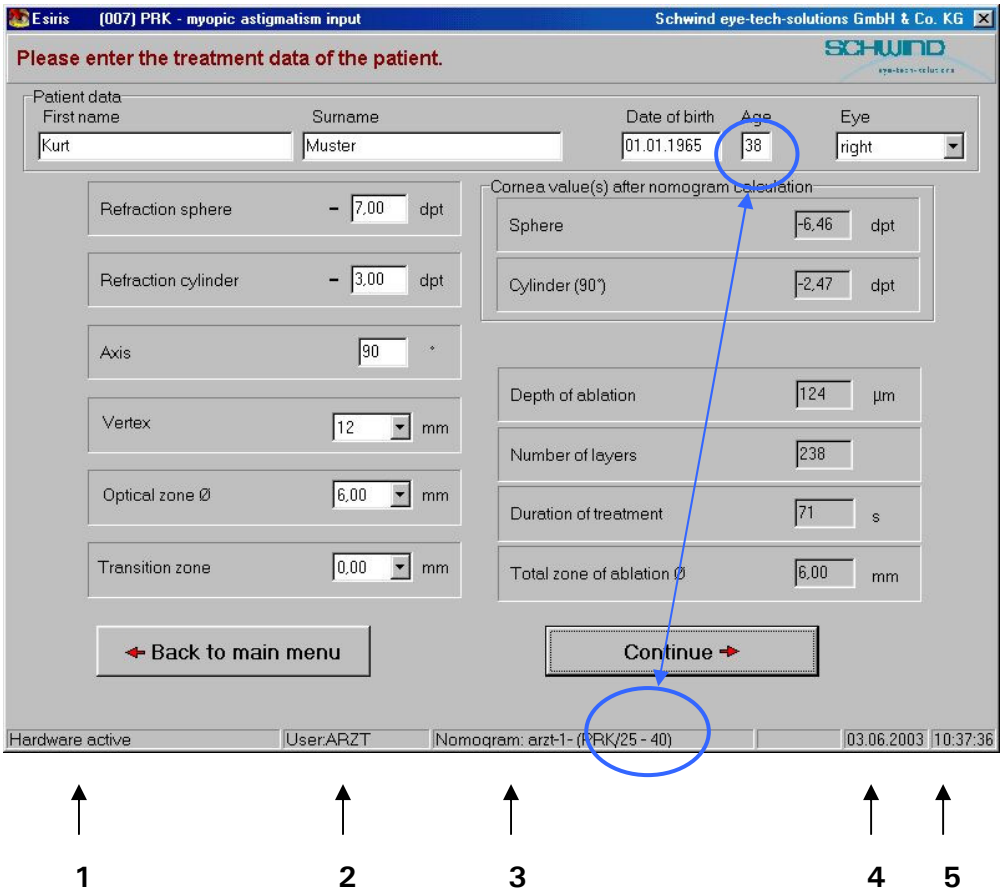
IMPORTANT NOTE

The myopic Astigmatism was selected as sample treatment.

8.3.3.1. Input of Patient and Treatment Data

After choosing the relevant type of treatment, a menu for entering the patient treatment data will appear (see the figure below).

In this menu patient data, refraction values, optical zone inputs can be entered.



Inputs required for treatment:

'First name'	Enter the patient's first name.
'Surname'	Enter the patient's surname.
'Date of birth'	Enter the patient's date of birth (DD.MM.YYYY).
'Age'	After input the patient's date of birth, the age of the patient appears automatically. To start a treatment, you have to enter either the date of birth or the age of the patient.
'Eye'	Define the eye to be treated.
'Refraction sphere'	Enter the intended spherical refraction change.
'Refraction cylinder''	Enter the intended cylindrical refraction change.
'Axis'	Enter the axis on the eye which should be treated.
'Vertex'	It is a distance in mm between the cornea and the spectacle glass.
'Optical zone''	Enter the diameter of intended ablation zone in mm.
,Transition zone'	It is an extended transition zone. It causes an extension of the optical zone and will increase the ablation depth by 5%.

The 6 information lines on the right side of the input menu (see below) indicates the corresponding values to the inputs you entered. The values are calculated by the system.

Cornea values after nomogram calculation:

'Sphere'	Indicates the corneal sphere refraction after the Nomogram calculation. If the values for sphere and cylinder result in a mixed astigmatism, the second cylinder axis will be displayed. In this case the field print will change and the axis will be shown in parentheses ( ), preceded by the symbol + or – as appropriate. The change of the sphere and cylinder parameter after nomogram calculation will usually not be shown. When desired, however, the changes can be shown in this field.
'Cylinder (90°)'	Indicates the corneal cylinder refraction after the Nomogram calculation. For treatment of mixed astigmatism, the first cylinder axis will also be displayed. In this case the field print will be change and the axis will be shown in parentheses ( ), preceded by the symbol + or – as appropriate.

The change of the sphere and cylinder parameter after nomogram calculation will usually not be shown. When desired, however, the changes can be shown in this field.

'Depth of ablation' The calculated ablation depth will be displayed.

'Number of layers' The calculated number of layers will be displayed. It consists of the fluence test value and the ablation depth.

'Duration of treatment' It indicates the time of the treatment in seconds. This is determined by the system and depends on the ablation per layer and the treatment parameters.

'Total zone of ablation' Indicates the diameter of the total ablation. It consists of the value of **'Optical zone'** and the double value of the **'Transition zone'**.

The bottom line (see Figure 46: Treatment menu myopic astigmatism for data input) displays the following information:

1- Information field for hardware feedback.

2- Logged user

3- Selected Nomogram

The nomogram won't be used until the age of the patient is entered (refer to Figure 46: Treatment menu myopic astigmatism for data input).

Before entering the patient's age the message in the treatment menu is: **"Nomogram: None"** (refer to Abbildung 47: Enter patient data - no nomogram). The nomogram can be used after entering the age of the patient.

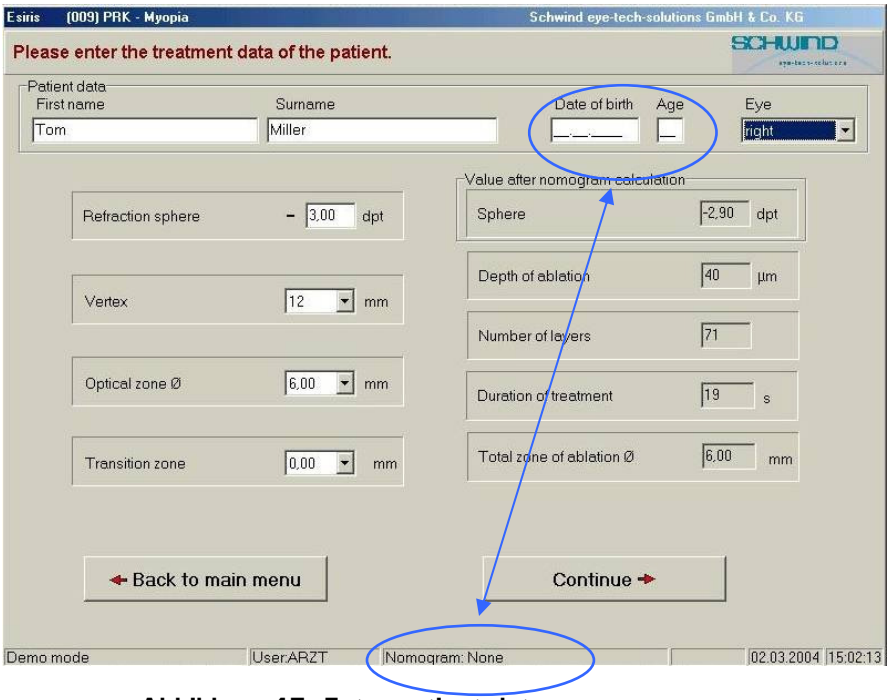


Abbildung 47: Enter patient data - no nomogram

IMPORTANT NOTE

Please check the correct nomogram selection according to the entered patient age (Figure 46: Treatment menu myopic astigmatism for data input).

If **date of birth** or **age** inputs are not entered, or these were deleted, no nomogram values are added.

4- Date

5- Time

After confirming the entries in the corresponding menus, the laser will be initialized. During the initialization you can hear some trigger pulses of the laser. These pulses are necessary to stabilize the energy and will not reach the patient's eye.

To return from the treatment menu to main menu, press the button **Back to main menu.**

To start the treatment, press the button **Continue.**

8.3.3.2. Execution of a PRK Treatment

When treatment is continued, a live image as a treatment screen will be displayed (see Figure 48: Start screen of a myopic astigmatism treatment).

The treatment will be performed in the live image screen. This screen is the same for all types of treatments and differs only in the top line, displaying the treatment which is performed.

The bottom line displays all data which have been entered in the treatment menu. Before treatment starts you have to ensure that all entries are correct.

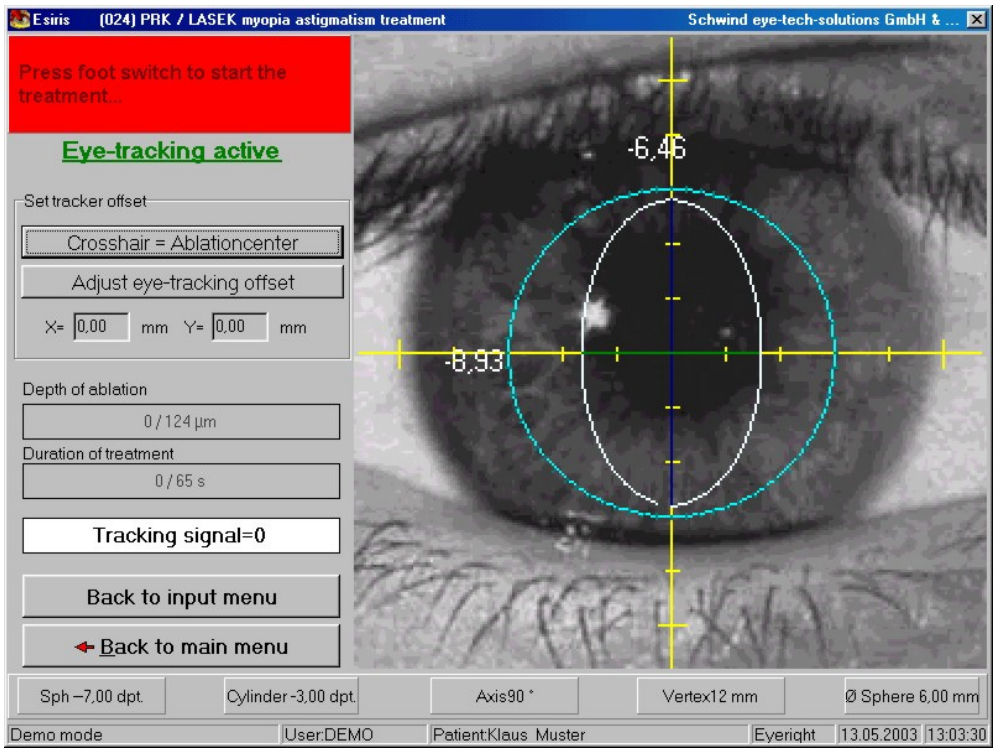


Figure 48: Start screen of a myopic astigmatism treatment

Explanation of the treatment screen

'Depth of ablation' It indicates the already ablated depth (left number). The right number shows the intended ablation depth.

'Duration of treatment' It indicates the duration of the treatment in seconds. It is determined by the system and depends on the ablation per layer and the treatment parameters, and especially on the depth of ablation. The left number shows the already reached treatment time, the right number shows the maximum treatment time.

On the right half of the monitor is displayed the live picture of the eye. The centre of the crosshair marks the centre of ablation with activated eye-tracker.

It is important that the eye is brought into the desired treatment position. For this purpose, the patient must be brought into position by operating the patient bed until crosshair of the live photo meets the centre of the desired ablation zone in order to take advantage of the full eye tracking range.

Focus of the height is achieved by merging the two position laser beams.

In the treatment screen, one can additionally see the axis of the astigmatism and the respective axis values.

As support for this representation, a white oval on the screen can be seen. The short axis of the oval always indicates the situation of the astigmatism.

This representation will not appear if a purely spherical treatment is performed.

After positioning of the eye, press the foot switch completely down (2 steps) to start the treatment procedure or to release the laser pulses.

When the foot switch pedal (completely or just one step) is released, the treatment is temporarily interrupted and can be continued by pressing pedal down again at the interrupted position.

Instructions for the user are always displayed in the headline of the treatment screen.

In the lowest screen line the values already entered by you are indicated again as a check.

To continue a treatment of the second eye (with new data input), press the button **Back to input menu.**

After completion of the treatment, press the button. **Back to main menu**.

After pressing these buttons, you will be asked if the treatment data should be printed.

A treatment print out contains all patient data entered before the surgery and also from the system calculated treatment data and system attitudes (see following figure).

SCHWIND eye-tech-solutions

Treatment

Method:	PRK / LASEK
Type of treatment:	myopic astigmatism

Laser serial number:	1234	Patient first name:	Klaus
Softwareversion:	2.5	Patient surname:	Muster
User:	ARZT2	Eye	right
Clinic / City:	NoClinic / NoCity	DOB / Age:	01.01.1965 / 38
Nomogram:	arzt2-2- (17.02.2003/13:39:48) (13.02.2003/10:09:03)	Date: Time:	20.02.2003 13:14:22

Input data

	Sph.	Cyl.	Axis	Vertex
PreOp. refraction	-7,00 dpt	-3,00 dpt	90 °	12,00 mm
Diameter opt. zone	6,00 mm	6,00 mm		
Diameter abl. zone	6,00 mm	6,00 mm		
Transition zone	0,00 mm	0,00 mm		
Cornea values	-6,46 dpt	-2,47 dpt	90 °	
Teached-in offset	0 µm 0°			

Treatment data

Min calculated treatment time	66 s	Time between first and last pulse	74 s
No. of eye tracking messages	2	Eye-Tracking Status	on
No. of pulses/layers	13275/229	Ablation:	100% 128/128 µm
No. of errors	0	Treatment finished	successfully

System data

Ablation per layer	0,557 µm/L.	Scanner drift offset	48µm 135°
Laser HV start treatment	45 %	Adjusted laser energy	11,0 mJ
Laser HV end treatment	41 %	Treatment since last fluencetest	1

Figure 49: Print out of patient and treatment data

The following chapter explains the functionality of the eye tracking.

8.3.3.3. Eye Tracking

The EYE TRACKING is a system which, with its assistance, fast eye movements become automatically balanced.

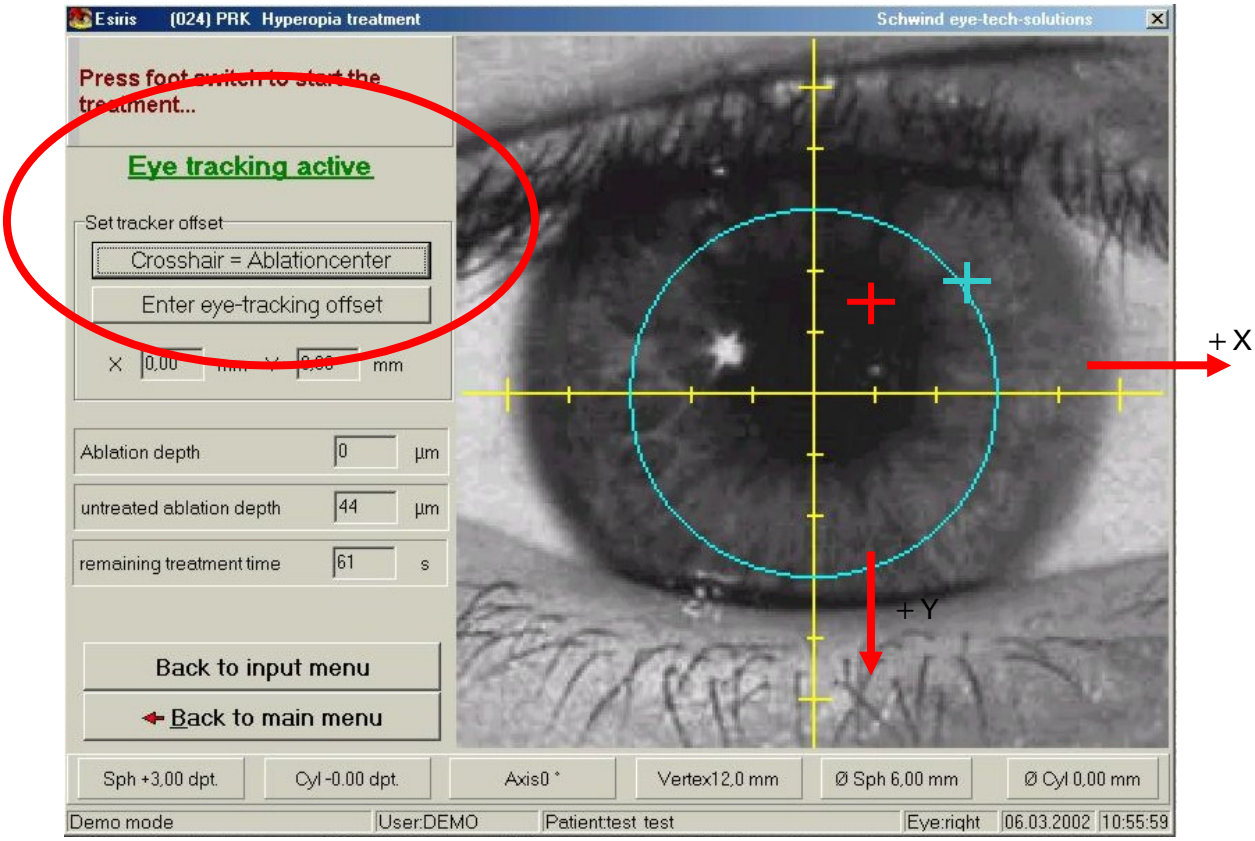


Figure 50: Functioning of the eye tracking

The EYE TRACKER calculates the center of the pupil from the live picture. This point of reference is represented on the screen with a red cross. The RED CROSS represents the pupil's centre and is the reference point for the treatment. When the eye moves, the RED CROSS follows the movement so the ablation centre is always at the centre of the pupil.

A GREEN CIRCLE on the edge of the pupil shows the area that the pupil was detected and also moves with the eye and the RED CROSS.

A TURQUOISE-COLOURED CIRCLE on the live-picture of the patient eye marks roughly the adjusted optical zone. Be aware that the zone of ablation might be larger than the optical zone "OZ". This circle does not move with the eye, however, but remains constant.

A beam guidance system inside the beam path of the laser steer the Excimer beam exactly to the required ablated position. If the pupil (marked with a RED CROSS) moves too far (+/- 1.5 mm) out of the centre, the system interrupts the treatment. A message will be displayed on the screen that the patient should fixate again, and asks if the EYE

TRACKING should be switched off. If the picture of the pupil is blurred, it is possible that the EYE TRACKER cannot find it.

The maximum tracking range is marked on the screen with a RED CIRCLE.

The software releases the laser for treatment only if the RED CROSS, which marks the centre of the pupil, is in the range of the RED CIRCLE.

To choose an ablation centre different from the pupil centre, fix the eye to the intended ablation centre corresponding to the large YELLOW CROSSHAIR. Press the button **Crosshair = Ablation Centre**, and a small TURQUOISE CROSS will be displayed. This is the new ablation centre. This procedure can be repeated as often as desired. The new ablation centre follows the movement of the eye as described above.

The RED CROSS remains visible and symbolises the centre of the pupil. The TURQUOISE CROSS shows the centre of the ablation which may be a different point.

Please pay attention:

When setting the decentration using the button **Crosshair = Ablation centre**, the tracking signal should be green and the value should be higher than 160. Otherwise an error message appears (refer to Figure 51: Error message eye-tracking) and the procedure must be repeated.

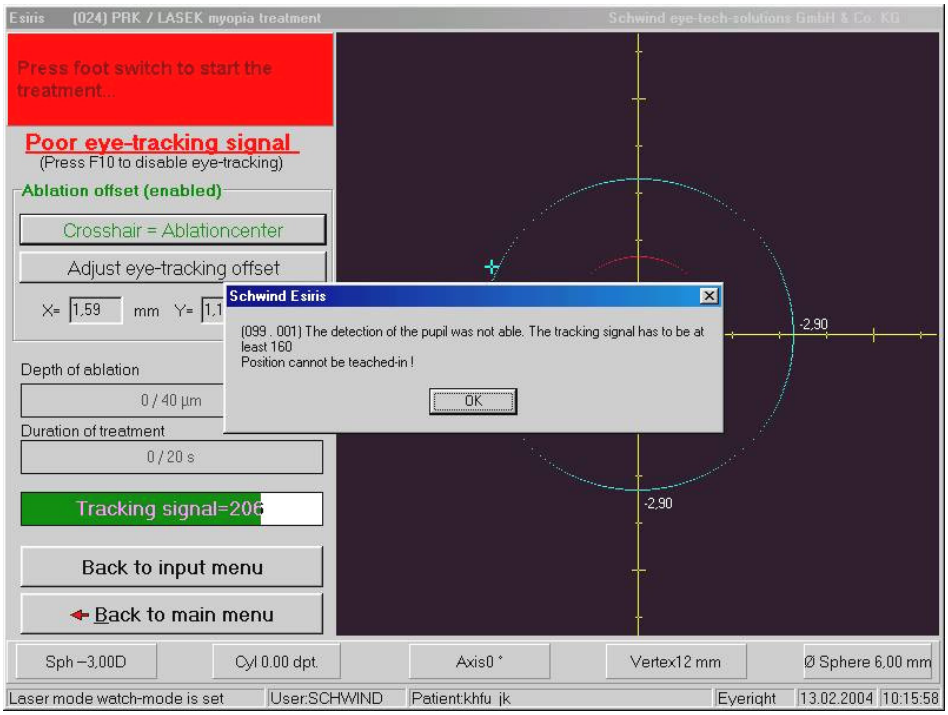


Figure 51: Error message eye-tracking

The ablation centre can be manually adjusted with the **Ablation Offset Input** button. In Figure 50: Functioning of the eye tracking, the adjustment direction, indicated by a RED ARROW, and the inscription of the axes (x/y), are highlighted. The TURQUOISE CROSS, indicating the ablation centre, would be an adjustment of ca. X = +0,5mm and Y = -0,5mm. It is also possible to adjust the TURQUOISE CROSS of the ablation centre with the

arrow keys in 10 µm increments, which will be immediately visible and will be displayed.

This input must be additionally confirmed after conclusion of the procedure by the pressing the Button **Confirmation offset input**.

Depending on the selected input method for the EYE TRACKER, the system marks a trained offset with a change of the display colour of the two upper Buttons to black offset on green.

If an EYE TRACKING problem should occur during treatment, the green message in the eye tracking status bar **'Eye Tracking Active'** changes to a red message **'Eye Tracking Not Active'**. As soon as the centre of the pupil can be detected again or is again in the treatment area with the foot switch pushed, the treatment continues immediately from the interrupted position.

As support for the appraisal of quality of the tracking signal, a bar diagram is displayed on the treatment screen. This display changes the colour from **green** to **red** when the pupil is not clearly recognized any longer (independently of whether the centre of the pupil is in the tracking range).

Very short interruptions in the way of milliseconds are barely noticeable; merely the sound of the laser pulse may change slightly.

It is possible to switch OFF the EYE TRACKING completely during the treatment by using the **F10** button.

IMPORTANT NOTE

During this treatment a switched OFF eye tracking cannot be switched ON again.

Both the input menu and the treatment screen are similar for all types of treatment, with a few differences. These differences between the individual treatments are described in following chapters.

8.3.3.4. Flap Countdown

Flap Countdown is an additional program which appears instead of the eye-tracker function Offset after the performed treatment. This Countdown may be used for various applications, e. g. in order to determine the exact waiting period between the flap flushes and the removal of the lid speculum.

Push the button **Start Flap Countdown** to activate the countdown of 120 seconds and the time counts down to 0 starting at 120 seconds. At the same time the blue bar moves from left to right.

The bar turns red for the last 5 seconds to indicate the end of the waiting period.

You may turn off this function at any time by pressing the button **Close Flap Countdown**.

IMPORTANT NOTE

Usually, this function is not active. You may enter any time other than 120 seconds. If you wish to use this function, the Service Department will be happy to release it for you.

8.3.4. PRK/LASEK Myopia

In this menu the patient data, refraction values, optical zone and transition zone can be entered.

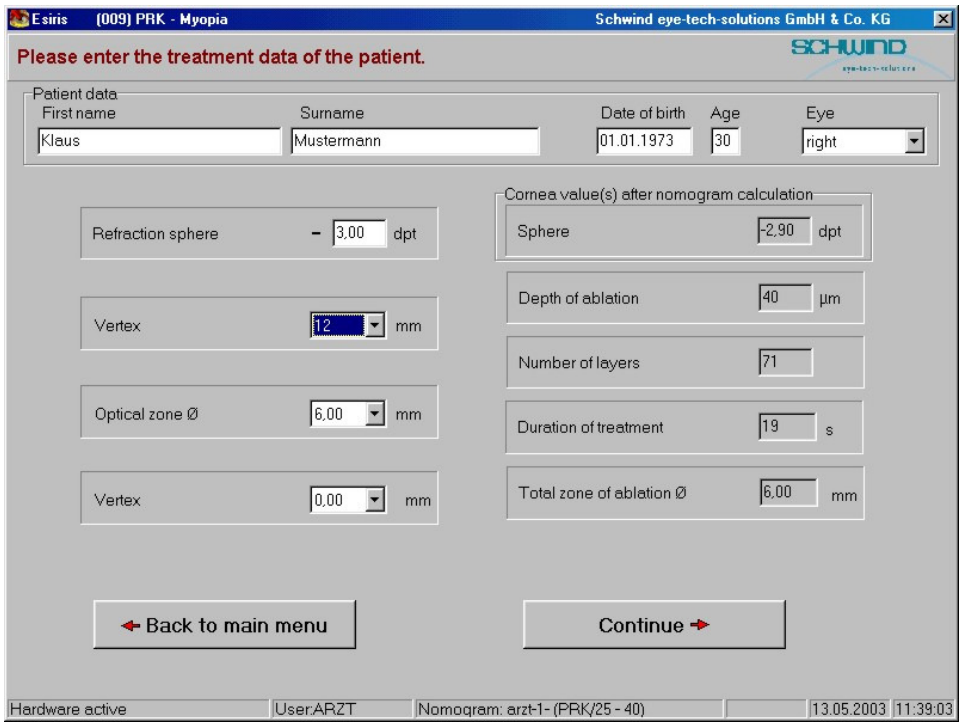


Figure 52: Treatment menu myopia for data input

IMPORTANT NOTE

The data input, the treatment screen, execution of a treatment and the eye-tracking function are explained in a sample treatment of myopic Astigmatism in chapter 8.3.3.

8.3.5. PRK/LASEK Myopic Astigmatism

IMPORTANT NOTE

Refer to chapter 8.3.3 Sample of PRK Treatment – Myopic Astigmatism.

8.3.6. PRK/LASEK Hyperopic Astigmatism

In this menu patient data, input of refraction values, vertex distance and ablation zone can be entered.

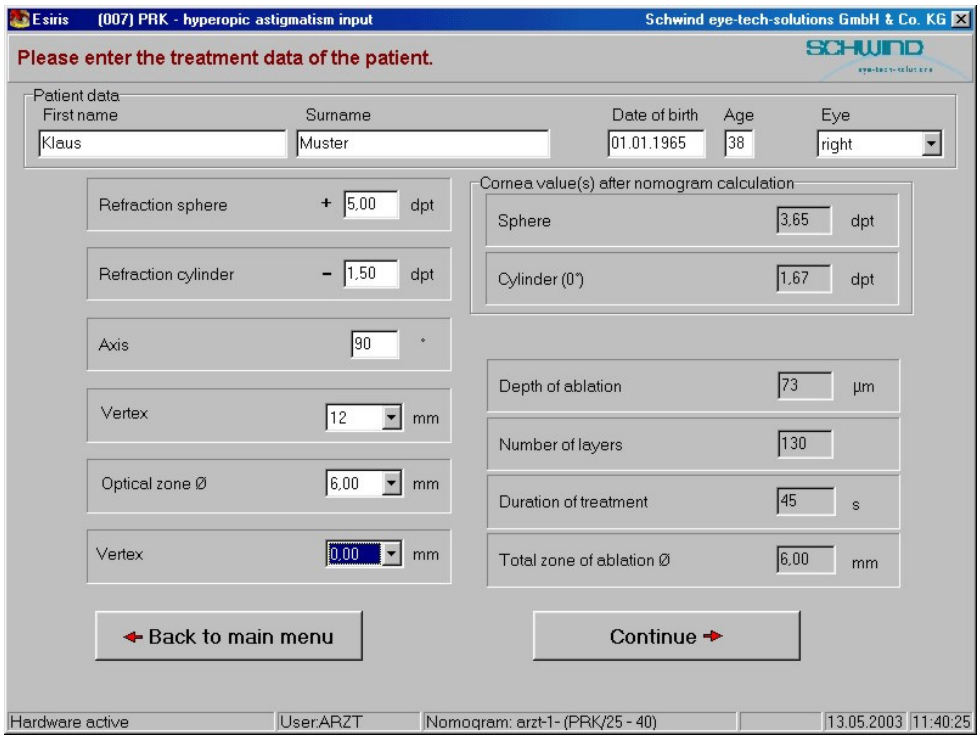


Figure 53: Treatment menu hyperopic Astigmatism for data input

IMPORTANT NOTE

The data input, the treatment screen, execution of a treatment and the eye-tracking function are explained in a sample treatment of myopic Astigmatism in chapter 8.3.3.

For all Hyperopia treatments (as opposed to Myopia), a change in the '**Transition Zone**' has no effect on the **Ablation Depth**.

8.3.7. PRK/LASEK Hyperopia

In this menu patient data, input of refraction values, vertex distance and ablation zone can be entered.

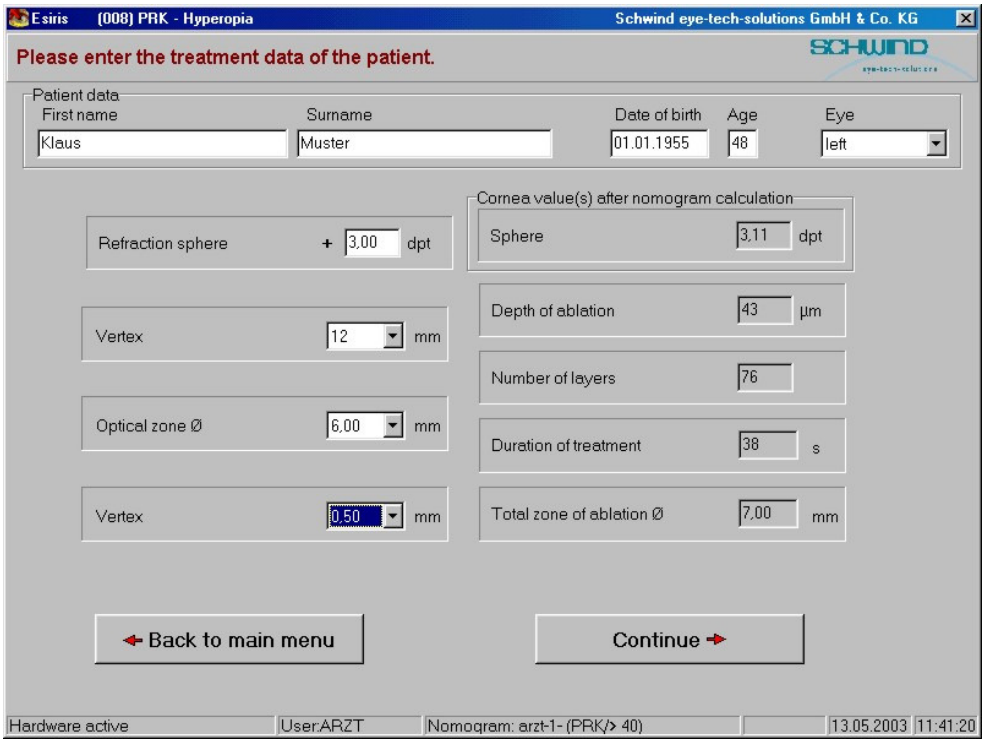


Figure 54: Treatment menu Hyperopia for data input

IMPORTANT NOTE

The data input, the treatment screen, execution of a treatment and the eye-tracking function are explained in a sample treatment of myopic Astigmatism in chapter 8.3.3.

For all Hyperopia treatments (as opposed to Myopia), a change in the **'Transition Zone'** has no effect on the **Ablation Depth**.

8.3.8. PRK/LASEK Bi-Toric Ablation

In this menu patient data, input of refraction values, vertex distance and ablation zone can be entered.

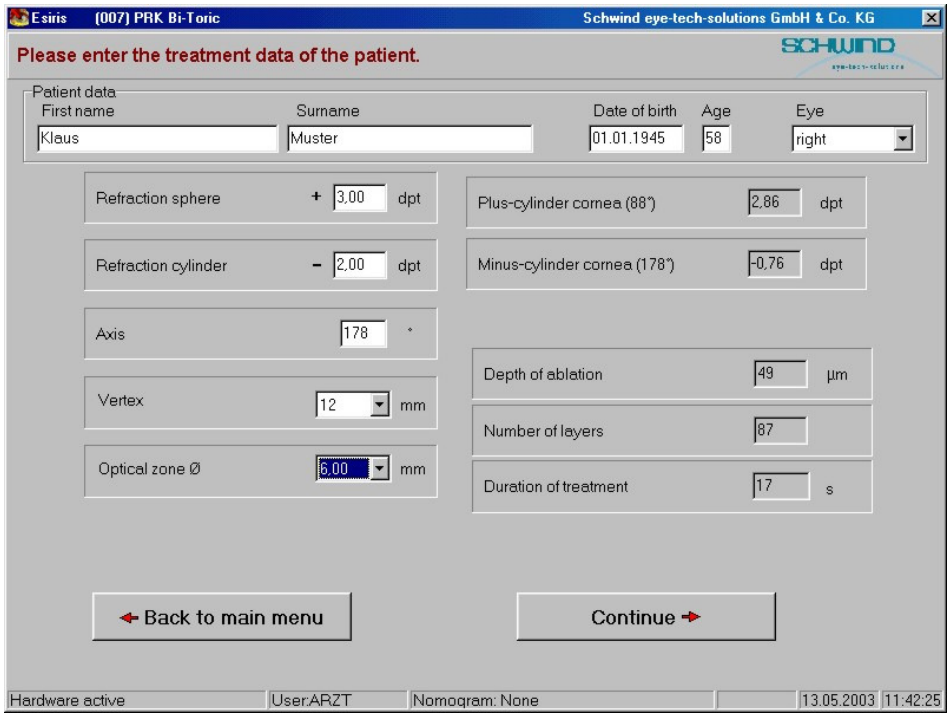


Figure 55: Treatment menu Bi-Toric for data input

IMPORTANT NOTE

The data input, the treatment screen, execution of a treatment and the eye-tracking function are explained in a sample treatment of myopic Astigmatism in chapter 8.3.3.

Additional data input required:

‚Plus-cylinder cornea' It is a refraction change of treated, positive cylinder. The axis of the cylinder will be additionally shown in parentheses ( ).

‚Minus-cylinder cornea' It is a refraction change of treated, negative cylinder. The axis of the cylinder will be additionally shown in parentheses ( ).

The calculation of these two positive and negative cylinders is carried out according to a fixed formula, which is explained in the OP manual.

Both cylinders are turned against each other around 90°.

8.3.9. PRK/LASEK Cross Cylinder Ablation

In this menu patient data, input of refraction values, vertex distance and ablation zone can be entered.

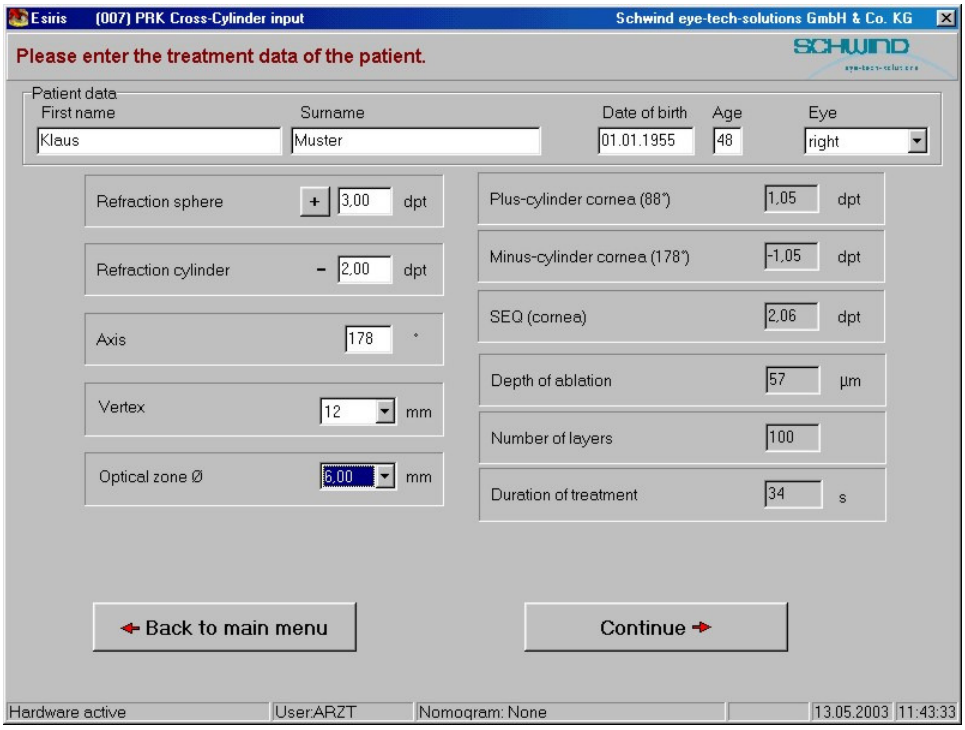


Figure 56: Treatment menu Cross Cylinder for data input

IMPORTANT NOTE

The data input, the treatment screen, execution of a treatment and the eye-tracking function are explained in a sample treatment of myopic Astigmatism in chapter 8.3.3.

Additional buttons for data input:

‚Plus-cylinder cornea' It is a refraction change of treated, positive cylinder. The axis of the cylinder will be additionally shown in parentheses ( ).

'Minus-cylinder cornea' It is a refraction change of treated, negative cylinder. The axis of the cylinder will be additionally shown in parentheses ( ).

"Refraction sph. Equivalent .Cornea (SEQ)"

The spherical equivalent is calculated by the input values of the sphere and the cylinder (see OP manual).

Contrary to all other treatments, the **'Spherical Equivalent'** is not taken into consideration in the individual axises. It is represented as a numerical value only at the left edge of the treatment screen on the live picture.

Regarding the calculation of the cylinder and the sphere, please refer to the OP manual.

8.4. LASIK Treatment

In the LASIK treatment the operation and handling of the individual treatments (myopia, myopic astigmatism, hyperopic astigmatism, hyperopia, bi-toric ablation, cross cylinder ablation) corresponds to the handling of the PRK treatments. The only difference between the Lasik menu and the standard PRK menu is that you can input different nomograms.

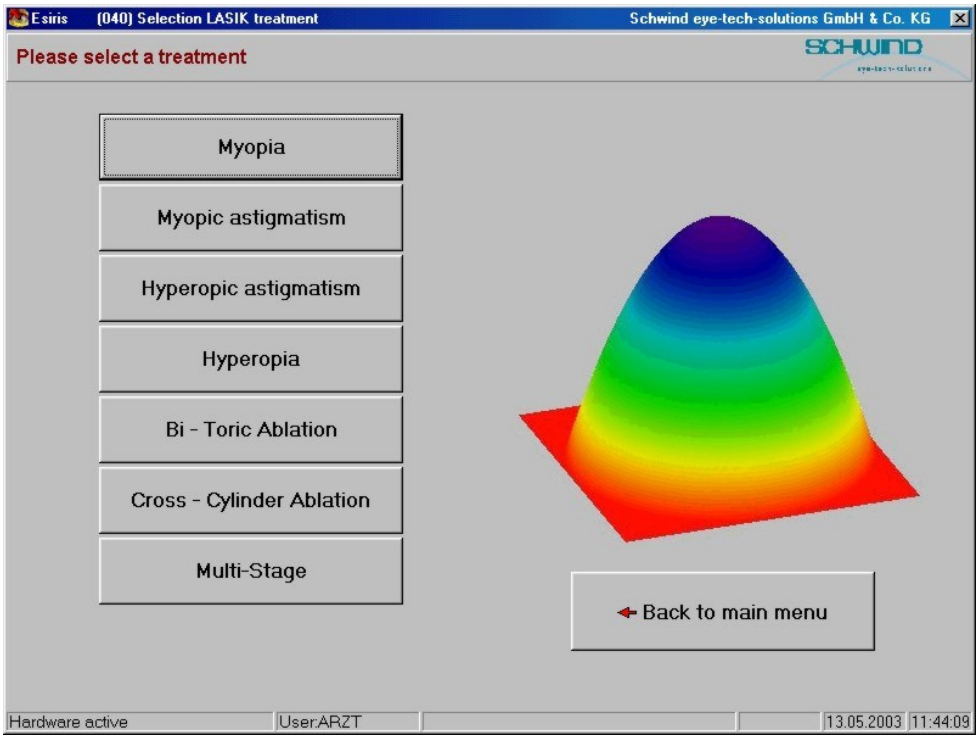


Figure 57: Lasik menu

8.5. Input of Patient Data from the Data Base

8.5.1. General

Now, in order to facilitate the administration of data, there is the possibility to enter your data into a data base and to transmit the information to the ESIRIS via a storage medium. This data may be used as a basis for a treatment with the ESIRIS and afterwards the data with the surgery information is routed to the data base. You may also include all pre-operative data and then process all data with statistic tools.

This data base which is especially developed for the ESIRIS is not part of the ESIRIS delivery program and has to be ordered separately.

8.5.2. Selection of a Patient for Treatment

After activating the button **Read patient data (on disk)** the dialogue window data base import menu appears. You may now select the patient who is to be treated.

First select the storage medium in the window. '**Please select the drive'** (A: floppy disk drive and E: USB memory stick). In this window you may have to select a subdirectory.

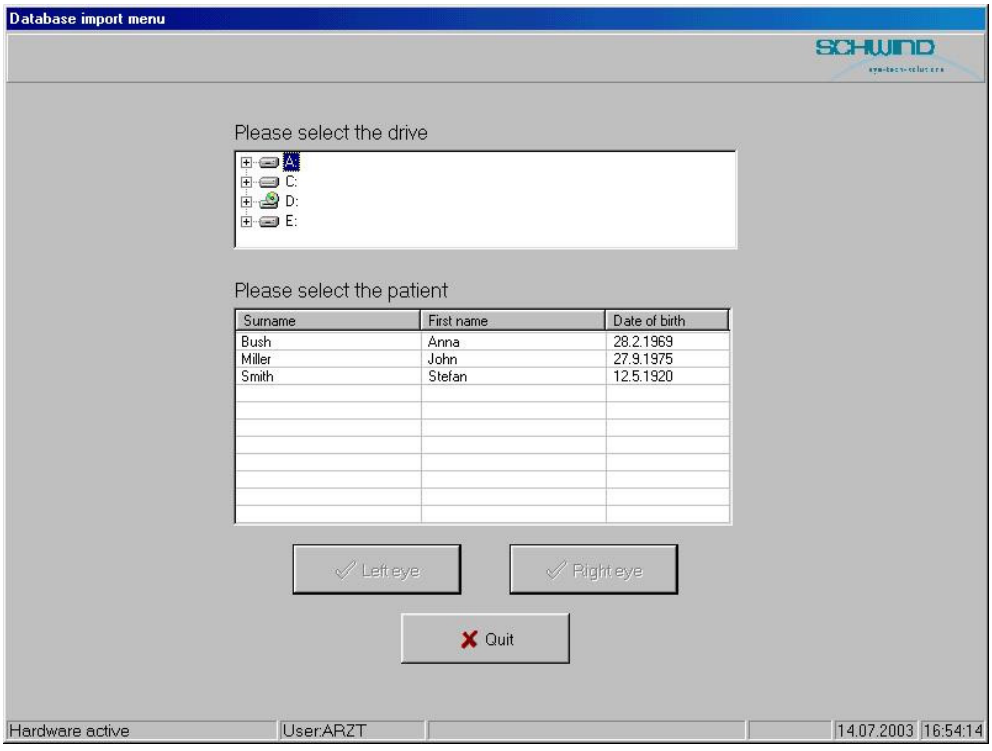


Figure 58: Data base import menu

When the drive and the subdirectory have been chosen correctly, a list with patient names will appear. Please select a patient with a mouse click. The name of the selected patient will appear in blue and at the same time the buttons for the eye (right or left) are engaged.

When pushing the button for the left eye, the software inputs data of the patient's left eye and returns to the input menu.

IMPORTANT NOTE

Please check if the correct patient and the correct eye had been selected. .

The menu also gives the opportunity to correct input data as sphere, cylinder, diameter of the treatment, etc. (refer to chapter 8.2.2 and 8.3.3.1)

Engage the button **Continue** to proceed to the treatment monitor. The treatment may be initiated after the self-test of the laser has been performed. (refer to chapter 8.3.3.2)

After the treatment has been completed press the button **Back to main menu.** Now you can print the data.

After confirmation **of Left (Right) eye treated. Continue with the right (left) eye?** all data for the second eye are automatically loaded.

If you confirm **yes** you will get to the main menu.

CAUTION!

All transmitted files are labelled with a check sum to avoid transmission errors. When the software indicates an error message stating that there is an error, all data from the data base has to be generated again.

IMPORTANT NOTE

Never remove the storage medium while data is transferred or during treatment (disk or USB- memory stick). This may lead to irreparable loss of data. The input or recording process is indicated at the USB memory stick by quick flashing of the LED. For safety reasons removal or input of storage media may only be performed in the main menu.

8.6. Performing ORK Treatments

8.6.1. General

The abbreviation **ORK** stands for **Optimized Refractive Keratectomy**.

First the data has to be input into an additional program ORK and a shot profile has to be established prior to treating a patient with topographic or wavefront guided data. The shot profile is entered via a data carrier to the ORK menu. Treatment is then performed according to the shot profile.

Shot profiles for true topography guided treatments and shot profiles based on corneal wavefront or aberrometry have to be generated with the ORK program.

This ORK software especially developed for the ESIRIS is not part of the ESIRIS delivery program and has to be ordered separately.

8.6.2. Select a Patient for Treatment

When pressing the button **ORK** the ORK menu is activated. In this menu you may select the respective drive with the data for treatment e.g. (A: floppy disk drive or E: USB memory stick) (see Figure 59: Selection of ORK shot profile). Files with the extension ***.abr** or ***.sht** are loadable by the software.

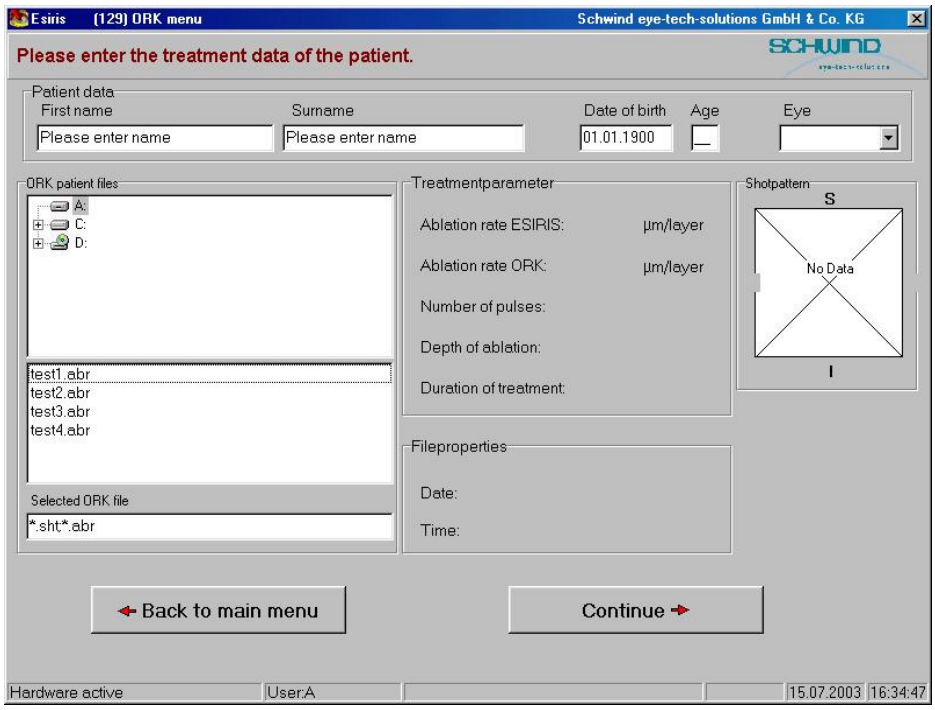


Figure 59: Selection of ORK shot profile

The desired treatment may be selected via mouse click and is highlighted blue. At the same time a shot profile is generated from the data carrier. This takes a few seconds. Once the procedure is finished the patient data, treatments parameters and file features together with the shot profile are displayed in colour on the monitor. (see Figure 60: ORK file input).

Data that has not been generated from the latest ORK version may not be processed. In this case you must enter the age or date of birth together with the eye which is to be treated.

If the button **Additional information** is pressed, an additional list with data for that particular patient is displayed. (see Figure 61: ORK file input with additional data).

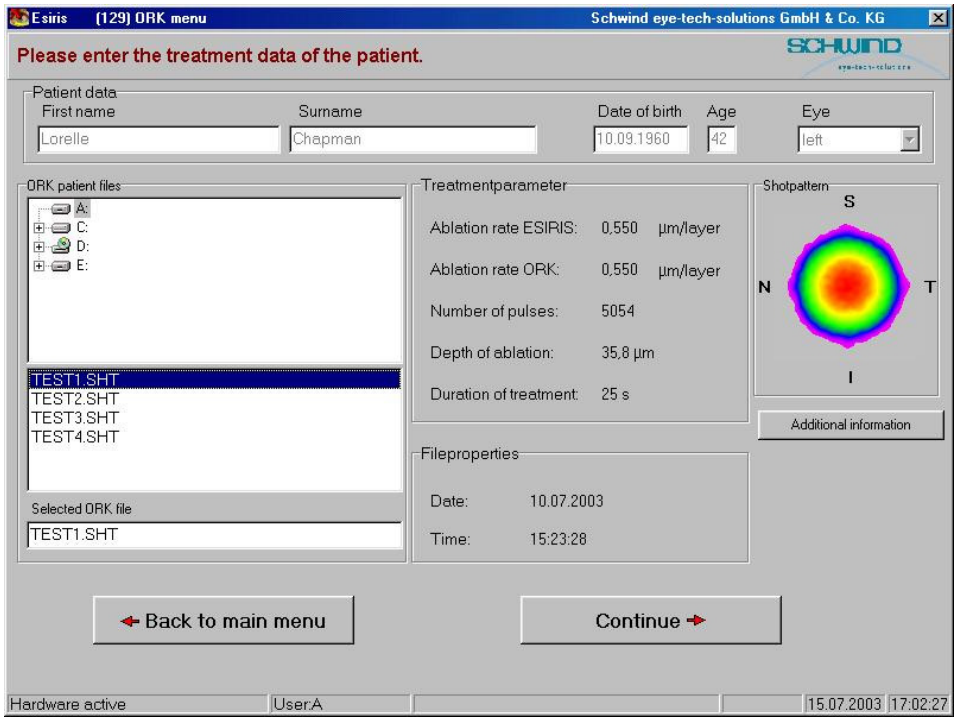


Figure 60: ORK file input

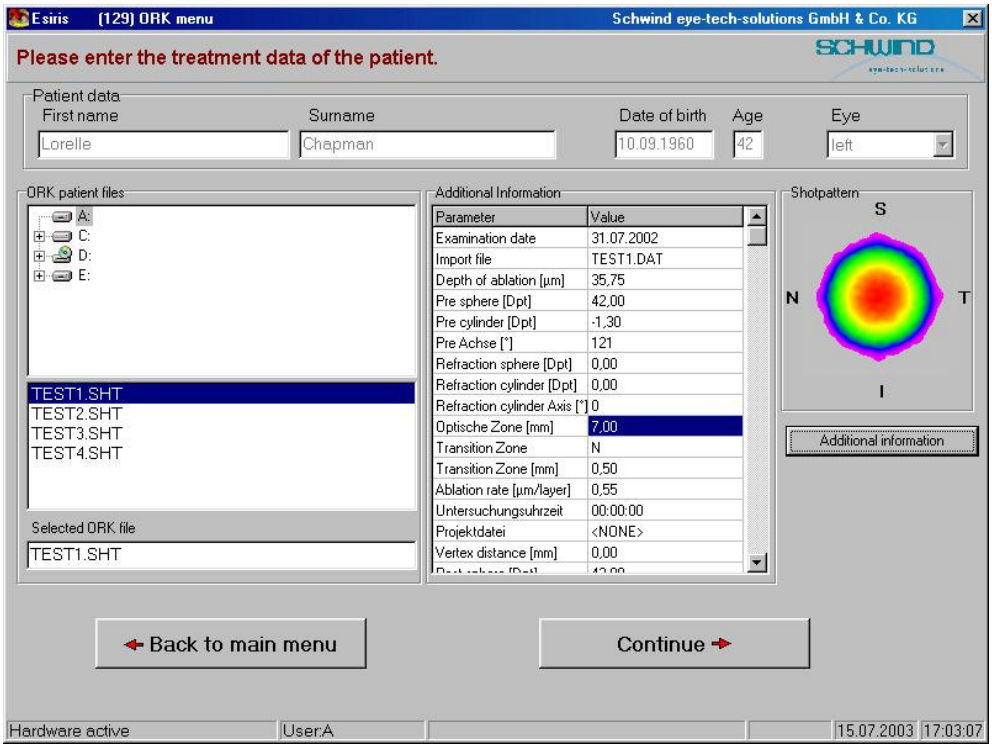


Figure 61: ORK file input with additional data

It is possible to view the complete list of data step by step via the scroll bar.

The button **Continue** activates the treatment window. Treatment will be started after the system check.

In opposite to the standard treatments you can not enter the decentration in the upper left corner, it is replaced by a coloured presentation of the shot profile (see Figure 62: Treatment screen of the ORK menu). If you press the foot switch, each laser pulse position is displayed with a white dot in the coloured picture. This white dot represents the center of the spot and not the whole spot itself.

In addition, prior to treatment the alignment of the profile may be compared with the live picture by markings N = nasal, S = superior, T = temporal und I = interior.

The progress of the treatment may be read from the treatment status bar. It is displayed in percentage and relates to the number of pulses given.

Analogous to the treatment monitor of the standard treatment the quality of the tracker signal is displayed as a bar diagram when the eye-tracker is activated.

Below you will find the name of the patient and see which eye has been treated.

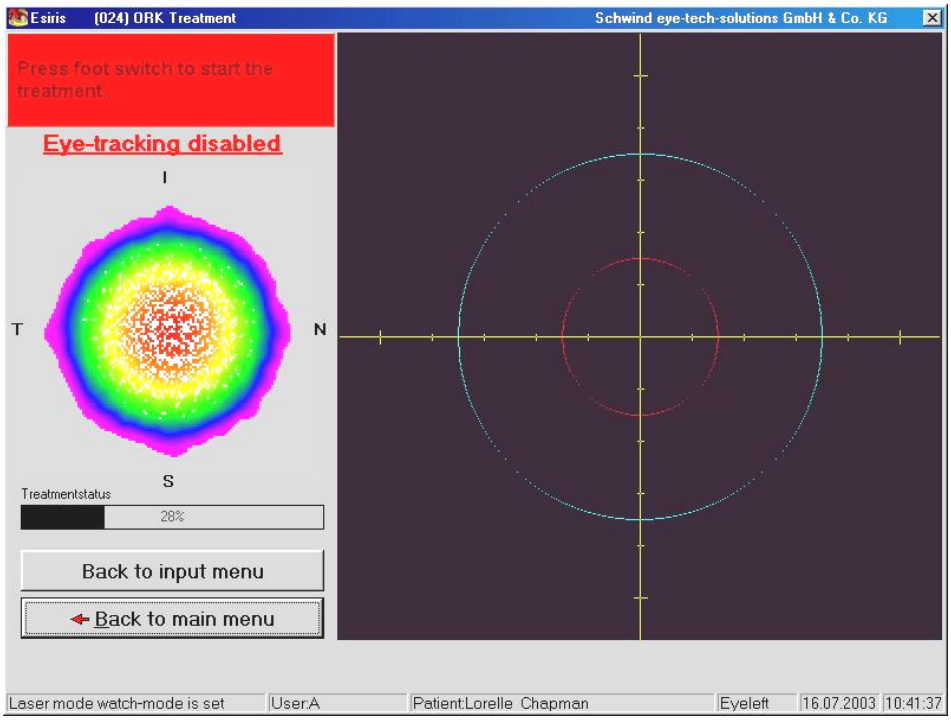


Figure 62: Treatment screen of the ORK menu

After the end of the treatment, you may close the menu with the **Back to main menu"**button and print the data on paper.

IMPORTANT NOTE

Since all shot profiles that are generated from the ORK software have been established with an expected ablation rate of the laser, it may occur that the ablation rate assumed for the ORK treatment does not correspond to that of the ESIRIS system. So it would not be possible to continue with this treatment.

CAUTION!

All transmitted files are labelled with a check sum in order to exclude transmission errors. The data of the ORK software has to be generated again, if the software indicates a respective error message.

IMPORTANT NOTE

Never remove a storage medium (floppy disk or USB memory stick) while data is being input or during treatment. It may result in irreparable loss of data. The input or recording process is indicated at the USB memory stick by quick flashing of the LED. Removal or input of storage media may only be performed in the main menu for safety reasons.

8.7. Recovery Function

8.7.1. General

In case treatment has been terminated by accident or intentionally, you may resume treatment from where it had been terminated via the restore function.

8.7.2. Restore

All buttons in the main menu appear red after treatment had been terminated. This warning function remains until another menu is activated or until you continue treatment by activating the button **Recovery**.

When engaging the button **Recovery,** a list of all terminated treatments with the patients' name appears indicating which eye had been treated, day and time of terminated treatment, and how many percent of the treatment had been performed succesfully. (see Figure 63: Restore menu).

Select a patient with a mouse click. The selected patient is highlighted in blue. You may now continue treatment when activating the button **Continue treatment**. In the following menu you may have to check all patient data again (refer to chapter 8.2.2 and 8.3.3.1) and the button **Continue** takes you to the treatment menu. After the warming up phase, you may continue treatment with the foot switch (refer to chapter 8.3.3.2).

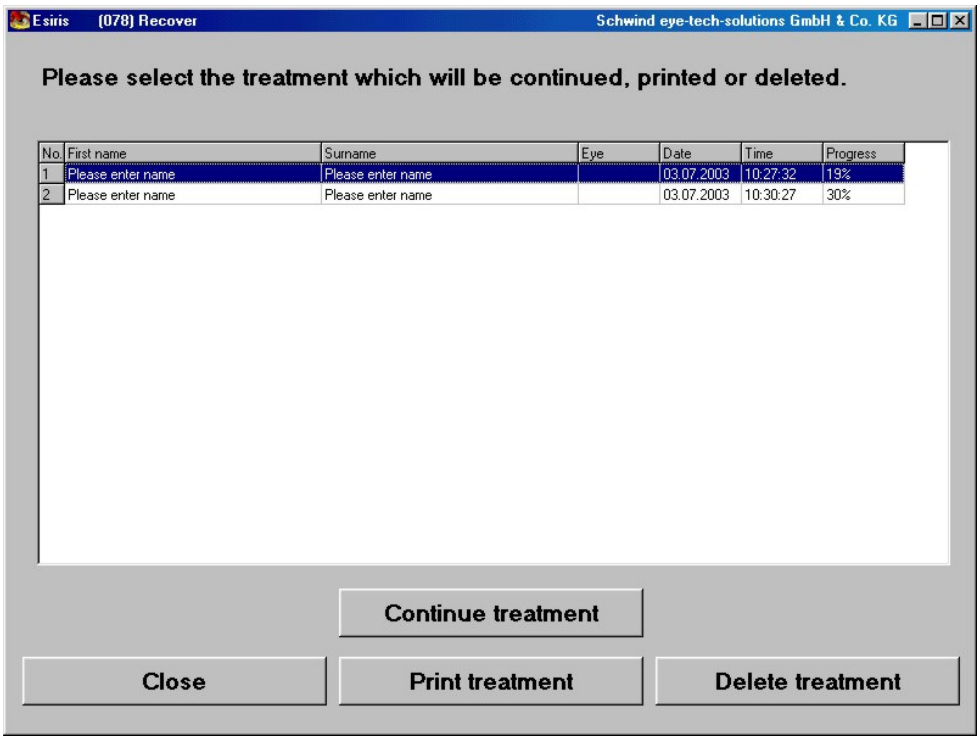


Figure 63: Restore menu

The data of the selected terminated treatments may be printed again when activating the button **Print treatment.**

The selected terminated treatments are removed from the menu with the button **Delete treatment.**

IMPORTANT NOTE

If treatments are entered via the data base or if they are terminated ORK treatments, then treatments should only be continued when the original storage medium with the relevant file has been inserted.

8.8. Accounting Routine Program

The program ‚Accounting routine' can be started from the ESIRIS Main Menu using the **'Help'** function (see Figure 64: Main menu – function ‚Help').

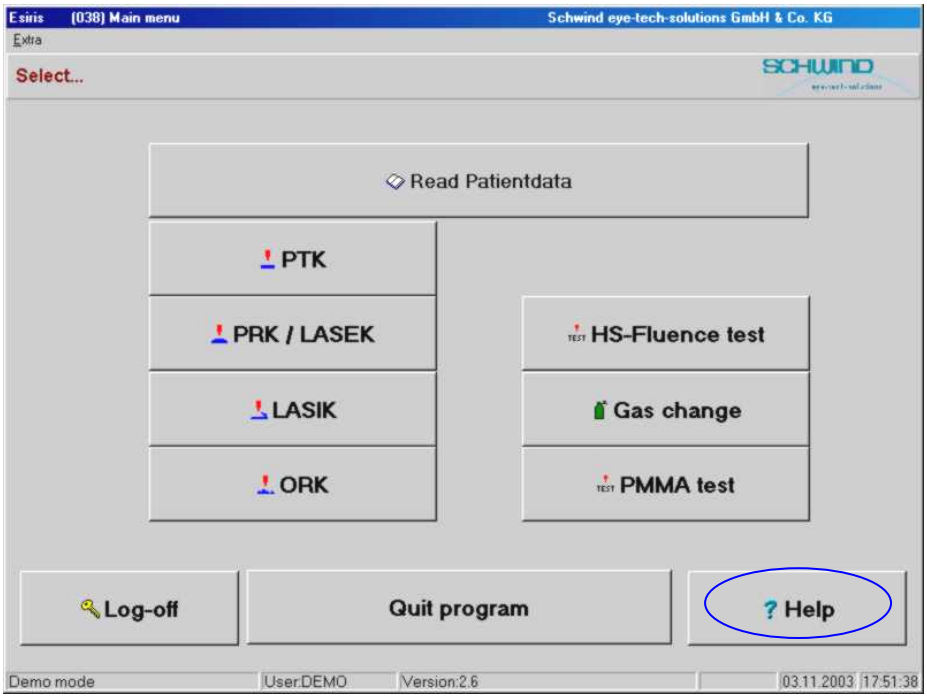


Figure 64: Main menu – function ‚Help'

After pressing the button **Help,** the information window appears, in which the function **'Accounting routine'** can be chosen.

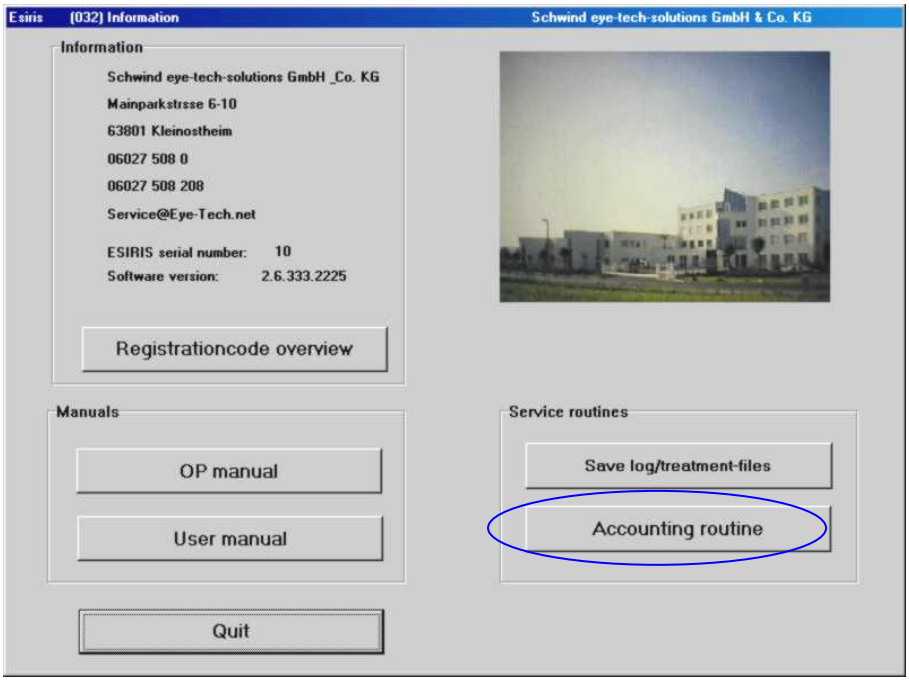


Figure 65: Help menu – window ‚Information'

Pressing the button **Accounting routine** starts a small external program. This announces itself with the reference to insert a disk into the drive assembly.

(Drive A:). This is to be also accomplished by the user.

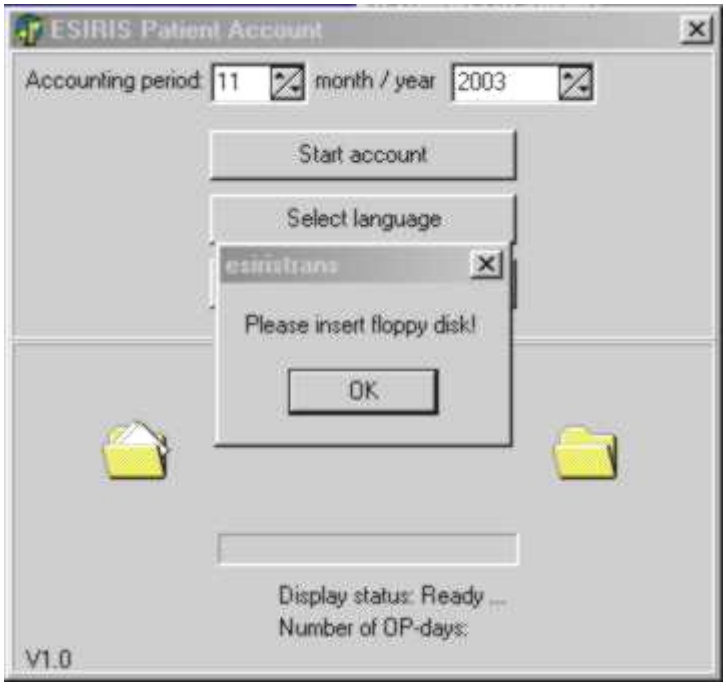
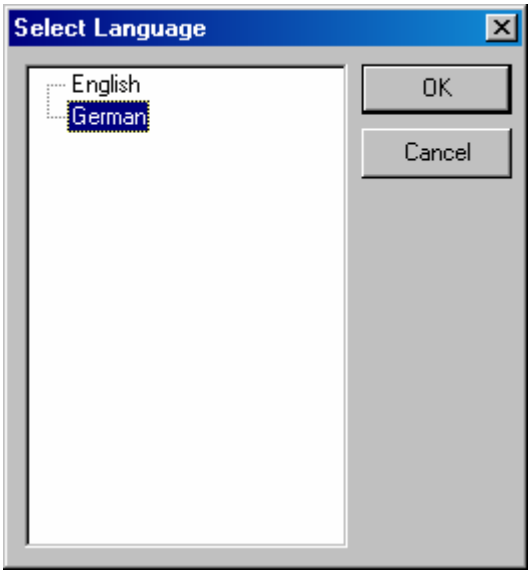


Figure 66: Menu ‚Patient account' – insert floppy disc

After confirming with the **OK** button, the following window appears:

Figure 67: Menu ‚Patient account' – select language

Pressing the button **Select language** offers the choice between English and German language.



In the top of the menu **'Patient account'** the month and year for the accout period can be selected. The period which should be accounted for must be individually selected.

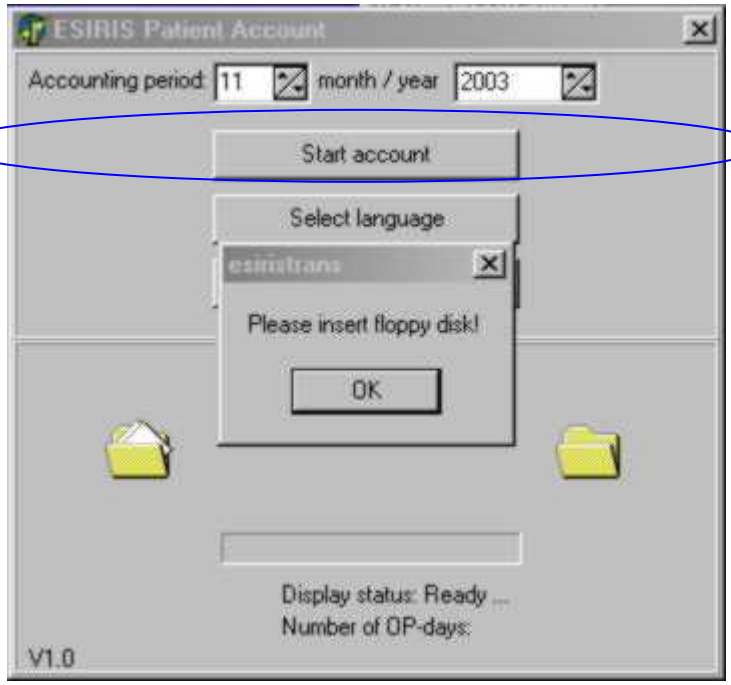


Figure 68: Menu ‚Patient account' – start accout

After setting the data and pressing the button **Start account** all settlement data will be automatically stored on the disk.

An additional information is presented during copying in the display status indicator.

After completion of the data transfer a reporting window appears that the copying process is final. Pressing the **OK** button will return you to the patient account program.

After pressing the **Quit** button you can return to the window '**Help'** of the ESIRIS software.

9. CLEANING AND MAINTENANCE

IMPORTANT NOTE

The user of the system does not need to perform any maintenance tasks except gas changes and surface cleaning.

9.1. Cleaning Procedures

9.1.1. General

When cleaning and disinfecting the surface of the unit the following should be observed:

- Be sure that no liquid cleaning agents enter into the system.
- To wipe off the fluid use a clean, dry and lint-free cloth.
- Do not clean the optics on the lower side of the optic arm cover. This will be done by the Service engineer using a special cleaning fluid
- Do not touch any optical surfaces, as this can lead to system malfunctions.

CAUTION / WARNING

Damage of device! Danger of short circuit!

Routine cleaning and disinfection procedures should be performed when the device is switched off.

Cleaning and disinfection when device is not switched off can lead to damage of the device and / or to personal injury by a short circuit.

CAUTION!

Energy impairment of the laser beam!

Damage of device!

To clean the SCHWIND ESIRIS and the treatment room do not use any liquids containing ammoniac or alcohol.

Ammoniac and alcohol reduce the energy of the laser beam and can cause varying of treatment results.

Aggressive detergents can damage the surfaces of the device or damage the medical device itself.

9.1.2. Cleaning of the Patient Bed

Normal dirt and grime may be cleaned using a moist (not wet!) cloth. Non-abrasive and non-aggressive cleaning agents may be used for more stubborn dirt and grime. Ordinary dry foam may also be used.

Material-preserving care is not necessary.

CAUTION!

Damage of device!

Cleaning activities may only be performed when the device is turned OFF. Allow the device to dry before operating.

Cleaning and disinfection when the device is not switched off device can lead to damage of device.

CAUTION!

Damage of medical device!

Do not use ether, acetone or concentrated liquids on painted surfaces. They can damage the surfaces.

During cleaning, no cleaning agent or water may enter the device. They can damage the medical device.

9.1.3. Cleaning and Sterilisation of Operating Microscope

Cleaning:

To clean the operating microscope please observes the following:

- If required, the housing parts can be cleaned with a dry cloth.
- Optical surfaces may be cleaned with a clean linen cloth that is free from any detergent residues.
- At longer intervals painted surfaces may be cleaned with a damp cloth, as required. Use an aqueous solution of a commercial cleaning agent.
- Make sure that no water penetrates inside the microscope.

Sterilization

Sterilization of the caps can be done in an autoclave up to max. 134°C or in hot air up to 165°C. Please observe the directive in paragraph 4 of MPBetreibV (Medical Device Regulations) of 29th of June 1998 regarding the sterilization procedure. Exchange the caps in case of visible damage.

9.2. Maintenance

9.2.1. General

IMPORTANT NOTES

- All repairs and service works, as well as the regular technical inspections, will be carried out exclusively by Service Representatives of the SCHWIND eye-tech-solutions or service technicians specifically authorized by SCHWIND eye-tech-solutions.
- The carrying out of repair and service works by non-authorized personnel results in the nullification of warranty and liability claims. Furthermore, service works carried out improperly can result in the subjection of users and patients to potentially hazardous system malfunctioning.
- Appropriate maintenance of the equipment in the specified service intervals guarantees that no inadmissible radiation can be emitted from the equipment.
- Opening of the equipment is permitted only by trained maintenance staff.

9.2.2. Maintenance of the Patient Bed

The patient bed is generally free of maintenance.

9.2.3. Maintenance of Operating Microscope

Only properly trained and instructed personnel are permitted to service the microscope. Assemblies incorporating optical components must not be dismantled since re-assembly requires special calibration tools.

9.2.3.1. Troubleshooting and Remedies of Operating Microscope

Failure	Remedy
Blurring when changing magnification	Check the ocular setting and re-adjust. Re-adjust at maximum magnification
Blurring image	Re-focus the microscope

9.2.4. Exchange of Gas Supply

9.2.4.1. Premix Bottle in Gas Containment

One PREMIX bottle contains enough gas for approximately 130 gas fills.

The change of the gas bottle will be done by the service technician of the SCHWIND eye-tech solutions.

IMPORTANT NOTE

If the remaining pressure allows only 40 gas exchanges, a message on the screen will appear.

Please order a new gas bottle at your SCHWIND eye-tech solutions distributor or at SCHWIND eye-tech solutions directly.

9.3. Technical Security Check (TSC)

In order to ensure the error free function of the Excimer of laser, please let perform an annual technical security check (TSC).

Technical safety inspections will be carried out at regular intervals by Service Representatives of the SCHWIND eye-tech-solutions or service technicians specifically authorized by SCHWIND eye-tech-solutions and documented in the Medical Device Logbook (Medical Apparatus Book).

Should a TSC be performed, this will be indicated by the software. Additionally the date for the next TSC is displayed on the sticker at the screen.

Please contact SCHWIND eye-tech-solutions in order to coordinate the inspection date.

The safety inspections contain the exchange of accessories, wearing parts, disposable articles and the device interfaces used in connection with the deployment of the device whenever the safety of system use can be significantly influenced by these secondary components.

IMPORTANT NOTE

If inadequacies are found during the technical inspection, which can affect the safety of patients, users or third parties, the device may not be used until the deficiencies have been eliminated.

9.3.1. Test Protocol of Technical Security Check

The test protocol will be completed by the service technicians during the corresponding service intervals of the entire system.

9.3.2. Maintenance Intervals

Yearly inspections of the complete system by an authorized service technician are necessary

9.4. Lifetime

The expected lifetime of the SCHWIND ESIRIS Excimer laser system is 6 years when the device is operated according to its intended use and the regular safety inspections are fulfilled.

9.5. Disposal

Upon reaching the end of its lifetime, the ESIRIS is considered to be metal and electronic scrap and should be appropriately disposed of.

Prior to disposal, the laser tube must be pumped clean and flushed with helium 3 times.

The gas bottles are to be disposed of at the gas supplier.

10. APPENDIX

The following appendixes include details of the laser and precise descriptions intended to help the user better understand the system. They are not necessary for ordinary use and so they are not part of the main user manual.

10.1. Calculation Basis

10.1.1. Introduction

For correction of myopia and hyperopia on the human eye, it is necessary to flatten or rise the bending of the corneal surface. If an astigmatism should also be corrected, the bending of the cornea must be changed in two meridians.

Correction of Myopia R1 < R2 Correction of Hyperopia R1 > R2

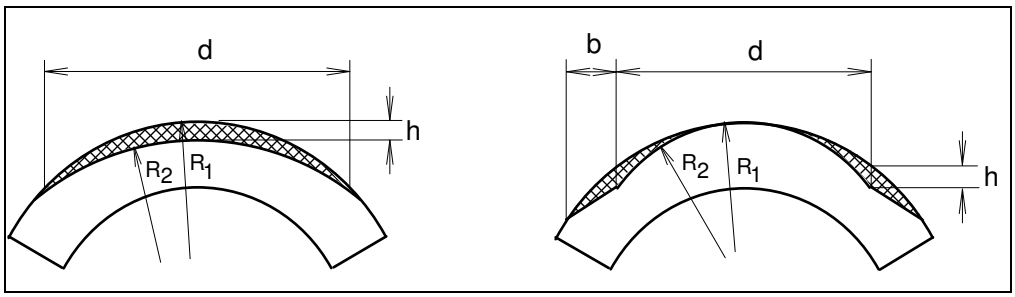


Figure 69: Schematic drawing of corneal correction in section.

The areas, treated with Excimer laser are darkened.

D = diameter of optical zone,

H = maximum depth of corneal incision

B = width of transition zone at hyperopic correction

R1 = bending radii of cornea before treatment

R2 = bending radii of cornea after treatment

Based on the bending change on the corneal surface, the power of refraction is changed by using the following formula:

$$D = (1-n)x(1/R2 - 1/R1)$$

Value for cornea (n = 1.376) has to be taken for refraction index. Unit for R is (m). Calculation of new corneal contour with above mentioned formula is very complex. A great simplification is the assumption of an even surface. A positive or negative lens is

made in this area. Consideration of actual corneal bending is not necessary. For adaptation of power density, which influences an area element to an angle of incidence, it is enough to use the normal bending radius of cornea (R = 7.8 mm).

10.1.2. Correction of Myopia

Geometric relations for myopia correction under simplified assumption of a flat basic area are displayed in Figure 70.

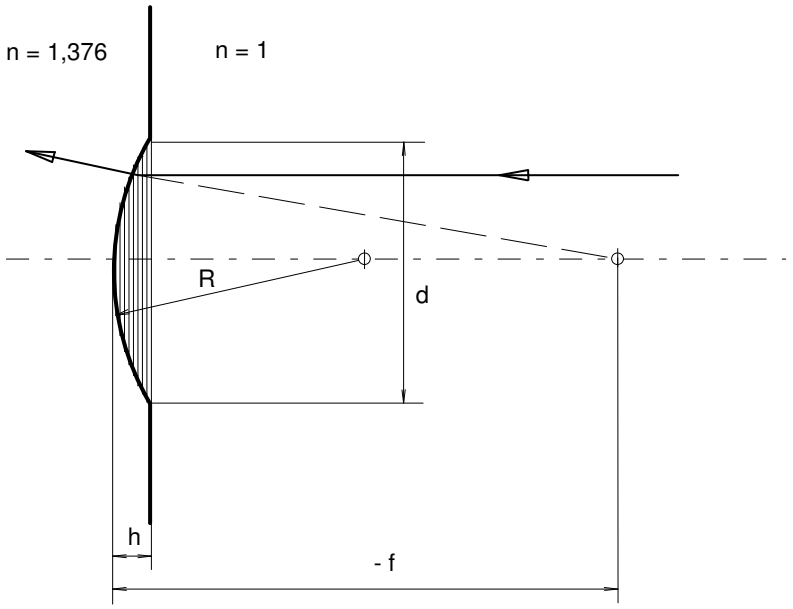


Figure 70: Simplified basis for calculation (even corneal surface) for Myopia

An area with negative focal distance is worked in to the basis area. The bending radius of this new limited area results on the following formula:

$$R[mm] = (1-n)/D = -376/D$$

The refractive index of cornea is taken with n = 1.376. The requested correction of refraction D has to be taken in dioptres [m-1].

For the correlation between diameter of optical zone d and the central ablation depth h the following formula is valid:

$$d = 2\sqrt{2hR - h^2} \approx 2\sqrt{2h^x(1-n)/d}$$

$$d^2 = 8h^x(1-n)/D$$

Diameter d of single ablation zones is pre-set through diameter input into the software.